I. GOAL

The goal of the Zyprexa Relprevv Patient Care Program is to mitigate the risk of negative outcomes associated with Zyprexa Relprevv post-injection delirium/sedation syndrome (PDSS) by:

1. ensuring Zyprexa Relprevv is prescribed only by certified prescribers, dispensed only by certified dispensers, and dispensed for use only in certified healthcare facilities with ready access to emergency response services, and dispensed for use only with documentation of safe use conditions;

2. informing healthcare providers and patients about the risks and the need for continuous observation of patients for at least 3 hours in certified health care facilities; and

3. establishing long-term safety and safe use of Zyprexa Relprevv through periodic monitoring for the risk of PDSS events and by enrolling all patients who receive Zyprexa Relprevv in the Zyprexa Relprevv Patient Care Program Registry.

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide is dispensed with each Zyprexa Relprevv prescription in accordance with 21 CFR 208.24.

The Medication Guide is part of the REMS and is appended.
B. Communication Plan

In accordance with the United States (US) Federal Food, Drug, and Cosmetic Act (FDCA) 505-1(e)(3), Lilly issued a Dear Healthcare Professional Letter which targeted psychiatrists as well as pharmacies within 60 days of product approval to support the implementation of the Zyprexa Relprevv Patient Care Program and the conditions of safe use. The Dear Healthcare Professional Letter was issued by mass mailing one time at product launch.

C. Elements to Assure Safe Use

Lilly commits to implement the following elements to assure safe use that includes requirements applicable to prescribers, pharmacies, and other third parties as described below:

   a. Lilly will ensure that prescribers enrolled in the Zyprexa Relprevv Patient Care Program are specially certified. Lilly will ensure that, to become certified, prescribers attest to their understanding of the Zyprexa Relprevv Patient Care Program requirements and the risks associated with Zyprexa Relprevv, have completed the mandatory Zyprexa Relprevv training, and have attested that they:
      i. understand the clinical presentation of post-injection delirium/sedation syndrome (PDSS) and how to manage patients should an event occur while using Zyprexa Relprevv;
      ii. understand that Zyprexa Relprevv should only be initiated in patients for whom tolerability with oral olanzapine has been established;
      iii. understand that Zyprexa Relprevv should only be administered to patients in health care settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection;
      iv. will enroll all patients in the Zyprexa Relprevv Patient Care Program Registry prior to prescribing Zyprexa Relprevv by completing the Patient Registration Form;
      v. will review the Zyprexa Relprevv Medication Guide with each patient or the patient’s legal guardian prior to prescribing; and,
      vi. understand that the Zyprexa Relprevv Patient Care Program coordinating center may contact the prescriber to resolve discrepancies, to obtain information about a patient, or to conduct occasional surveys.
   b. The certified prescriber will be retrained and recertified every 3 years from time of enrollment.
   c. Lilly may disenroll prescribers that are noncompliant with the program requirements.
d. Lilly will maintain a validated and secured database of all certified prescribers, as well as a database of the completed data forms. The database links each reported PDSS event to the enrolled patient and the associated prescriber.

e. The following prescriber materials are part of the REMS and are appended:

1. Healthcare Professional Training
2. Zyprexa Relprevv Patient Care Program Instructions Brochure
3. Prescriber Registration Form

2. Zyprexa Relprevv will only be dispensed by pharmacies and health-care settings under FDCA 505-1(f)(3)(C) who are specially certified under FDCA 505-1(f)(3)(B).

a. Lilly will ensure that to be certified to dispense Zyprexa Relprevv, each pharmacy and health-care setting will be enrolled in the Zyprexa Relprevv Patient Care Program. Lilly will ensure that to become enrolled the pharmacy and health-care setting staff have been educated about the requirements of the Zyprexa Relprevv Patient Care Program.

The education and enrollment process is comprised of the following steps that must be completed:

i. Each pharmacy and health-care setting where Zyprexa Relprevv is dispensed for use in other certain health-care settings will designate a representative who will review the Zyprexa Relprevv Patient Care Program Instruction Brochure. The designated representative will complete and sign the Pharmacy Registration Form or the Buy and Bill Registration Form. In signing the form, the representative is required to indicate that they understand and attest that:

a) I have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;

b) I will ensure that all appropriate pharmacy staff are trained and have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;

c) I will ensure that all appropriate pharmacy staff understand that Zyprexa Relprevv can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services that can allow for continuous patient monitoring for at least 3 hours post-injection;

d) I will ensure that pharmacy staff will verify that the patient is enrolled in the Zyprexa Relprevv Patient Care Program Registry prior to dispensing each prescription/refill by accessing the system;
e) I will ensure that pharmacy staff will not dispense Zyprexa Relprevv directly to patients;

f) I will ensure pharmacy staff report the date of each Zyprexa Relprevv dispensing to the Zyprexa Relprevv Patient Care Program; and

g) I understand that the Zyprexa Relprevv Patient Care Program coordinating center may contact the pharmacy to clarify information provided or obtain information about the patient.

ii. Each health-care setting where Zyprexa Relprevv is dispensed and administered to the patient will designate a representative who will review the Zyprexa Relprevv Patient Care Program Instruction Brochure. The designated representative will complete and sign the Healthcare Facility Registration Form. In signing the form, the representative is required to indicate that they understand and attest that:

a) I have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;

b) I will ensure that all appropriate staff are trained and have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;

c) I will ensure that all appropriate staff understand that Zyprexa Relprevv can only be dispensed for use in certain health-care settings (e.g., hospitals, clinics) that have ready access to emergency response services that can allow for continuous patient monitoring for at least 3 hours post-injection;

d) I will ensure the health-care setting has systems, protocols, or other measures to ensure that Zyprexa Relprevv is only administered to patients enrolled in the program and that patients are continuously monitored for at least 3 hours post-injection for suspected PDSS;

e) I will ensure that appropriate staff will verify that the patient is enrolled in the Zyprexa Relprevv Patient Care Program Registry prior to each injection by accessing the system;

f) I will ensure that the Medication Guide is provided to the patient or the patient’s legal guardian prior to each injection;

g) I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours; and

h) I understand that the Zyprexa Relprevv Patient Care Program coordinating center may contact the health-care setting to clarify information provided or obtain information about the patient.

b. Certified dispensers will be recertified every 3 years from the time of enrollment.
c. Lilly may disenroll dispensers that are noncompliant with the program requirements.

d. The following materials are part of the REMS and are appended:
   1. Pharmacy Registration Form
   2. Buy & Bill Pharmacy Service Provider Registration Form
   3. Zyprexa Relprevv Healthcare Professional Training
   4. Zyprexa Relprevv Reconstitution and Administration Training
   5. Zyprexa Relprevv Patient Care Program Instructions Brochure
   6. Healthcare Facility Registration Form

3. **Zyprexa Relprevv will be dispensed to patients with evidence or other documentation of safe-use conditions under FDCA 505-1(f)(3)(D).**

   a. Lilly will ensure that certified dispensers will verify that each patient is eligible to receive Zyprexa Relprevv prior to dispensing each prescription/refill of Zyprexa Relprevv by accessing the Zyprexa Relprevv Patient Care Program and ensuring the patient is enrolled in the Zyprexa Relprevv Patient Care Program Registry and the prescriber is certified.

4. **Each patient using Zyprexa Relprevv will be subject to certain monitoring under 505-1(f)(3)(E).**

   a. For each injection of Zyprexa Relprevv, the practitioner or health-care facility staff that administers Zyprexa Relprevv must monitor the patient continuously for at least 3 hours.

5. **Each patient using the drug will be enrolled in a registry under 505-1(f)(3)(F).**

   a. Lilly will ensure that certified prescribers enroll each patient treated with Zyprexa Relprevv in the Zyprexa Relprevv Patient Care Program Registry and assign a unique identifying number before Zyprexa Relprevv is dispensed to each enrolled patient. Unless otherwise excepted under section 5e, Lilly will ensure that, to become enrolled, each patient or patient’s legal guardian signs the Patient Registration Form indicating that:
      i. they understand that the patient must enroll in the Zyprexa Relprevv Patient Care Program Registry to receive Zyprexa Relprevv;
      ii. they agree to have patient information entered in the Zyprexa Relprevv Patient Care Program Registry;
      iii. the doctor has explained the risk and benefits of treatment with Zyprexa Relprevv;
      iv. they have received a copy of the Medication Guide;
v. they understand that the patient will be observed at the clinic for 3 hours after each injection;

vi. they understand that the patient must be accompanied from the health-care facility to their destination;

vii. they understand that the patient must not use heavy machinery for the rest of the day on which the injection was administered;

viii. they agree to seek medical care right away if the patient has a reaction such as excessive sleepiness, dizziness, confusion, difficulty talking, difficulty walking, muscle stiffness or shaking, weakness, irritability, aggression, anxiety, increase in blood pressure or convulsions;

ix. they agree to contact the physician if the patient has a reaction to Zyprexa Relprevv; and

x. they may be asked to complete occasional surveys about their understanding of the risks and benefits of treatment with Zyprexa Relprevv.

b. Lilly will ensure that health-care settings where Zyprexa Relprevv is administered record and submit the following information for each patient after each injection by completing either the Single or Multiple Patient Injection Form and returning this form to the Zyprexa Relprevv Patient Care Program coordinating center:

i. injection date and time;

ii. dose;

iii. verification that the patient was continuously observed at the healthcare facility for at least 3 hours;

iv. verification that the patient was alert, oriented, and absent of any signs and symptoms of PDSS prior to being released from the health-care facility;

v. verification that the patient was accompanied upon leaving the health-care facility;

vi. verification that the patient or the patient’s legal guardian was given a Medication Guide prior to this injection;

vii. any report of a PDSS event since the previous Zyprexa Relprevv injection; and

viii. verification that the health-care setting contacted the prescriber if the patient experienced a PDSS event.
c. Lilly will ensure that certified prescribers record and submit the following information for any report of PDSS in a patient administered Zyprexa Relprevv by completing the Post-Injection Delirium/Sedation Form and returning it to the Zyprexa Relprevv Patient Care Program coordinating center:

i. summary of the PDSS event, including signs and symptoms of any event and a detailed timeline of the course of events related to injection;

ii. demographic characteristics of the patient (age, gender, race, height, weight, medical conditions, geographical location);

iii. Zyprexa Relprevv dose;

iv. type and timing of interventional treatment or therapy administered;

v. outcome of the PDSS event;

vi. concomitant medications prior to and at the time of PDSS occurrence; and

vii. preexisting or concurrent medical conditions.

d. The following materials are part of the REMS and are appended:

1. Patient Registration Form
2. Single Patient Injection Form
3. Multiple Patient Injection Form
4. Post-Injection Delirium/Sedation Syndrome Form

e. In situations where a patient is under a court order for involuntary psychiatric treatment, which order permits the administration of medications without patient consent and/or against the patient’s wishes, and where no guardian has been appointed for the patient, such patient may be enrolled in the Zyprexa Relprevv Patient Care Program Registry without patient signature. However, the Patient Registration Form must clearly show that said court order is in place and the duration of the court order. The information required under section 5(a) iii should still be shared with the patient, and the provisions of sections 5b, 5c, and 5d shall still apply.

f. Patients enrolled under section 5e shall be considered enrolled only until such time that their court order for involuntary treatment terminates, or they are discharged from their involuntary commitment by their treatment team where permitted by applicable state law. Upon such termination or discharge, the patient must be re-enrolled in the Zyprexa Relprevv Patient Care Program pursuant to the requirements of section 5a to be eligible for continued treatment with Zyprexa Relprevv. In the alternative, if an involuntary commitment is extended by court order, a new Patient Registration Form should be requested reflecting the duration of the new order.
D. Implementation System

The Implementation System will include the following. Lilly will:

1) Maintain a validated and secured database of all certified dispensers, as well as a database of the completed data forms. The database links each reported PDSS event to the enrolled patient and the associated dispenser.

2) Review distribution data to assess compliance with the requirement that Zyprexa Relprevv is only dispensed by the certified dispensers.

3) Assess certified dispensers’ compliance with the requirement to dispense Zyprexa Relprevv for use in health-care settings that have ready access to emergency response services and can allow for continuous patient monitoring for at least 3 hours post-injection.

4) Based on evaluation of the implementation of elements to assure safe use provided for under Sections C2 and C3 above, and in the manner described in the REMS supporting document, take reasonable steps to improve implementation of these elements to meet the goals of the REMS.

E. Timetable for Submission of Assessments

Lilly will submit REMS assessments to the FDA annually on 29 October. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Lilly will submit each assessment so that it will be received by the FDA on or before the due date.
Single Patient Injection Form
Multiple Patient Injection Form
Post-Injection Delirium/Sedation Syndrome Form
Zyprexa Relprevv Patient Care Program Website
The goal of this presentation is to educate healthcare professionals in an effort to mitigate negative outcomes associated with ZYPREXA RELPREVV post-injection delirium/sedation syndrome (PDSS). Healthcare professionals include: physicians, nurses and any other professionals who will be involved with the care of the patient receiving the injection.

Please see the Prescribing Information and the Reconstitution and Administration Poster before using ZYPREXA RELPREVV.
ZYPREXA RELPREVV: Indication

- ZYPREXA RELPREVV is a long-acting atypical antipsychotic for intramuscular injection indicated for the treatment of schizophrenia.

For a list of symptoms and the complete diagnostic criteria for schizophrenia, see the Diagnostic and Statistical Manual of Mental Disorders, Ed 4, Text Revision (American Psychiatric Association; 2000).

ZYPREXA® RELPREVV™, also known as (olanzapine) For Extended Release Injectable Suspension, is the long-acting injectable form of ZYPREXA (olanzapine).

ZYPREXA RELPREVV is indicated for the treatment of schizophrenia and is administered by deep intramuscular gluteal injection.
ZYPREXA RELPREVV: Boxed Warnings

- Post-injection Delirium/Sedation Syndrome (PDSS):
  - Patients are at risk for severe sedation (including coma) and/or delirium after each injection and must be observed for at least 3 hours in a registered facility with ready access to emergency response services. Because of this risk, ZYPREXA RELPREVV is available only through a restricted distribution program called ZYPREXA RELPREVV Patient Care Program and requires prescriber, healthcare facility, patient, and pharmacy enrollment.

- Increased mortality in elderly patients with dementia-related psychosis:
  - Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
  - ZYPREXA RELPREVV is not approved for the treatment of patients with dementia-related psychosis.

If you prescribe ZYPREXA RELPREVV, you need to be aware that it carries a boxed warning for Post-Injection Delirium/Sedation Syndrome (PDSS). Patients who receive ZYPREXA RELPREVV are at risk for severe sedation (including coma) and/or delirium after each injection and must be observed for at least 3 hours in a registered facility with ready access to emergency response services. Because of this risk, ZYPREXA RELPREVV is available only through a restricted distribution program called ZYPREXA RELPREVV Patient Care Program and requires prescriber, healthcare facility, patient, and pharmacy enrollment.

Because the active ingredient of ZYPREXA RELPREVV is the same as oral ZYPREXA® (olanzapine), ZYPREXA RELPREVV also carries the same boxed warning as oral ZYPREXA regarding increased mortality in elderly patients with dementia-related psychosis. ZYPREXA RELPREVV is not approved for the treatment of patients with dementia-related psychosis.
Training Content

At the end of this training, you should be able to:

- Differentiate between ZYPREXA RELPREV (olanzapine for extended release injectable suspension) and ZYPREXA IntraMuscular (olanzapine for injection) to avoid medication errors
- Understand the dosing options with ZYPREXA RELPREV
- Know the common adverse events associated with ZYPREXA RELPREV and how to monitor patients for metabolic changes
- Identify a post-injection delirium/sedation syndrome (PDSS) event in your clinical practice
- Know the conditions of safe use and how to manage the risk of PDSS
- Know what to do in case a PDSS event occurs
- Understand basics of the ZYPREXA RELPREV Patient Care Program

At the end of this training, you should be able to:

- Differentiate between ZYPREXA RELPREV (olanzapine for extended release injectable suspension) and ZYPREXA IntraMuscular (olanzapine for injection) to avoid medication errors,
- Understand the dosing options with ZYPREXA RELPREV,
- Know the common adverse events associated with ZYPREXA RELPREV and how to monitor for metabolic changes
- Identify a post-injection delirium/sedation syndrome event in your clinical practice,
- Know the conditions of safe use and how to manage the risk of post-injection delirium/sedation syndrome
- Know what to do in case a post-injection delirium/sedation syndrome event occurs.
- And finally, understand the basics of the ZYPREXA RELPREV Patient Care Program.
It should be noted that there are 2 types of injectable olanzapine, and they are intended for very different purposes. ZYPREXA RELPREVV is the long-acting salt formulation of olanzapine, olanzapine pamoate, and is administered every 2 to 4 weeks for the treatment of schizophrenia in adults. ZYPREXA IntraMuscular is the rapid-acting injectable form of olanzapine and is indicated for the immediate treatment of AGITATION associated with schizophrenia or bipolar mania.

It is very important not to confuse these two products, so please also make note of the visual differences in the products and product packaging as well as differences in injection technique and dosing.
ZYPREXA RELPREVV is a combination of olanzapine and pamoic acid in the form of a crystalline salt, which is insoluble in water but has very low solubility in muscle. When injected into the gluteal muscle, the salt then dissolves slowly at the site of the injection. This results in a slow and sustained release of olanzapine into the bloodstream, allowing for administration once every 2 or 4 weeks.

The pamoic acid component allows for this extended delivery but has no known pharmacological activity and is excreted unchanged. It has been used in a number of other approved products.
ZYPREXA RELPREVX: Product Characteristics

- Deep intramuscular gluteal injection only
  - 19 gauge 1.5" needle (2" needle may be used for obese patients)
  - Not for deltoid injection
- 3 vial strengths – 210 mg, 300 mg, 405 mg
  - Describes the available olanzapine in that vial
  - Reconstitute with the diluent provided to a fixed concentration of 150 mg/mL
  - 24-hour medication stability in vial once reconstituted
  - No refrigeration needed
- Inject immediately after withdrawing from vial

Review the ZYPREXA RELPREVX Reconstitution and Administration Training Video and the Reconstitution and Administration Poster before reconstituting the product

- ZYPREXA RELPREVX is administered by deep intramuscular gluteal injection only, using a 19 gauge, 1.5" needle to ensure a deep gluteal injection and to prevent the suspension from clogging the needle. A 2" needle may be used for obese patients. Please note that ZYPREXA RELPREVX is not approved for deltoid injections.

- ZYPREXA RELPREVX is provided as olanzapine pamoate powder, which comes in 3 vial strengths: 210, 300, and 405 mg. These strengths describe the amount of olanzapine provided in each vial. The product must be reconstituted using the diluent provided, which contains a wetting agent, a thickening agent, and an isotonic agent to allow for easier reconstitution and administration as well as patient comfort. Both the powder and the diluent are stored at room temperature and are reconstituted to a fixed concentration of 150 mg of olanzapine per milliliter.

- Once reconstituted, the suspension is stable in the vial for up to 24 hours and does not require refrigeration. However, if the suspension is not used immediately, it should be shaken to resuspend before being withdrawn into the syringe for administration.

- Once the product has been withdrawn from the vial, it should be injected immediately.

- Review the ZYPREXA RELPREVX Reconstitution and Administration Training Video and the Reconstitution and Administration Poster before reconstituting the product

Reference ID: 4417451
Dosing of ZYPREXA RELPREVV

Recommended Dosing for ZYPREXA RELPREVV Based on Correspondence to Oral Olanzapine (ZYPREXA) Doses

Target Oral Olanzapine (ZYPREXA) Dose
- 10 mg/day
- 15 mg/day
- 20 mg/day

Starting ZYPREXA RELPREVV Dose
- 210 mg/2 weeks or 405 mg/4 weeks
- 300 mg/2 weeks

Maintenance ZYPREXA RELPREVV Dose After 8 Weeks of Treatment
- 150 mg/2 weeks or 330 mg/4 weeks
- 210 mg/2 weeks or 405 mg/4 weeks
- 300 mg/2 weeks

For complete safety profile, including boxed warnings, see the full Prescribing Information.

Transition
- How does ZYPREXA RELPREVV correspond to an oral olanzapine dose?
- This figure depicts the approximate dose correspondence between oral olanzapine and ZYPREXA RELPREVV

Key points
- Dosing of ZYPREXA RELPREVV is described by the number of milligrams of active ingredient—olanzapine—provided in each injection; for instance, a 150 mg ZYPREXA RELPREVV dose contains 150 mg of olanzapine
- After the first 8 weeks of treatment when plasma concentrations approach steady state levels, there is a clear dose correspondence with oral olanzapine
  - This correspondence can be estimated by dividing the number of milligrams by the number of days in the dosing interval; thus:
    - 150 mg of ZYPREXA RELPREVV given every 2 weeks or 300 mg given every 4 weeks corresponds to approximately 10 mg/day of oral olanzapine
    - 210 mg of ZYPREXA RELPREVV given every 2 weeks or 405 mg given every 4 weeks corresponds to approximately 15 mg/day of oral olanzapine
    - 300 mg of ZYPREXA RELPREVV given every 2 weeks corresponds to approximately 20 mg/day of oral olanzapine
- During the first 8 weeks of treatment, a loading dose strategy is recommended for the 10 or 15 mg/day patients
- Please refer to the Package Insert for complete dosing information
Comparable Safety Profile Between ZYPREXA RELPREVV and Oral Olanzapine: 24-Week Study

<table>
<thead>
<tr>
<th>Treatment-Emergent Adverse Events: Incidence &gt;2% with ZYPREXA RELPREVV</th>
<th>ZYPREXA RELPREVV (N=599) %</th>
<th>Oral Olanzapine (N=322) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with ≥1 TEAE</td>
<td>52.1</td>
<td>46.9</td>
</tr>
<tr>
<td>Weight Increased</td>
<td>7.2</td>
<td>7.5</td>
</tr>
<tr>
<td>Insomnia</td>
<td>7.2</td>
<td>4.0</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>4.3</td>
<td>4.3</td>
</tr>
<tr>
<td>Anxiety</td>
<td>4.0</td>
<td>2.8</td>
</tr>
<tr>
<td>Headache</td>
<td>3.2</td>
<td>4.3</td>
</tr>
<tr>
<td>Somnolence</td>
<td>3.8</td>
<td>2.8</td>
</tr>
<tr>
<td>Injection site pain</td>
<td>2.3</td>
<td>0.9</td>
</tr>
<tr>
<td>Hallucination</td>
<td>2.3</td>
<td>0.6</td>
</tr>
</tbody>
</table>

None of these events were statistically significantly different

Adverse events reported with ZYPREXA RELPREVV were consistent with adverse events reported with oral olanzapine, taking into account method of administration. Data on file, Lilly Research Laboratories, ZYP20081111D.

For complete safety profile, including boxed warnings, see the full Prescribing Information.

Now we will look at the safety profile for ZYPREXA RELPREVV. The overall safety of ZYPREXA RELPREVV is similar to that of oral olanzapine, with the exception of injection-related events. In a study of over 900 stabilized patients comparing ZYPREXA RELPREVV and oral olanzapine, there were no significant differences in the most commonly reported adverse events. Weight gain was the most commonly reported event in both groups.
Data from the 24-week study comparing ZYPREXA RELPREVV to oral olanzapine also indicated no significant differences in the percentage of patients experiencing a potentially clinically significant change from baseline in weight, fasting glucose, fasting triglycerides, fasting total cholesterol, or fasting LDL cholesterol.

The results suggest that the metabolic profile is comparable to that of oral olanzapine.
Looking at the weight change seen in this study in more detail, there was no difference in the pattern of weight gain or loss in patients treated with ZYPREXA RELPREVV versus those treated with oral olanzapine. The mean weight change in both groups was a gain of approximately one kilogram.
In a 24-week randomized, double-blind, fixed-dose study comparing 3 doses of ZYPREXA RELPREVY in patients with schizophrenia, statistically significant differences among dose groups were observed for the safety parameters below.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>150 mg/2 wk</th>
<th>405 mg/4 wk</th>
<th>300 mg/2 wk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>0.67</td>
<td>0.89</td>
<td>1.70*</td>
</tr>
<tr>
<td>Prolactin (μg/L)</td>
<td>-5.61</td>
<td>-2.76</td>
<td>3.57**</td>
</tr>
<tr>
<td>Fasting triglycerides</td>
<td>6.5%</td>
<td>9.8%</td>
<td>24.5%*</td>
</tr>
</tbody>
</table>

* Mean change
** Change from normal at baseline to high at any time (%)

Comparison of doses in this study revealed differences on 3 safety parameters: weight, prolactin, and fasting triglycerides, with patients treated with the highest ZYPREXA RELPREVY dose, 300 mg every 2 weeks, experiencing the greatest mean increases in weight and prolactin and also being more likely to experience an increase in triglyceride levels from normal to high.
Metabolic Monitoring

- Hyperglycemia, in some cases associated with ketoacidosis, coma or death, has been reported
  - Olanzapine appears to have a greater association with increases in blood glucose levels than some other atypicals*
  - Monitor patients on olanzapine regularly for worsening of glucose control.
  - Consider the benefits/risks when giving olanzapine to patients with diabetes and to those with borderline hyperglycemia
  - Patients starting treatment with olanzapine should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment
  - Conduct fasting blood glucose testing in patients who develop symptoms of hyperglycemia during treatment

* Relative risk estimates are inconsistent, and the association between atypical antipsychotics and increases in blood glucose appear to fall in a continuum

- Because the active ingredient of ZYPREXA RELPREVUV is the same as oral olanzapine, clinicians should follow the same guidance with regard to metabolic changes that they would for the oral formulation.

- Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including olanzapine. Relative risk estimates are inconsistent, and the association between atypical antipsychotics and increases in blood glucose appear to fall in a continuum. Olanzapine appears to have a greater association with increases in blood glucose levels than some other atypicals.

- Patients on olanzapine should be monitored regularly for worsening of glucose control. Benefits and risks of olanzapine should be considered when prescribing the product to patients with diabetes and to those with borderline hyperglycemia.

- Patients starting treatment with olanzapine should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment.

- Fasting blood glucose tests should be conducted in patients who develop symptoms of hyperglycemia during treatment
Metabolic Monitoring

- **Hyperlipidemia**
  - Undesirable lipid alterations have been observed. Clinical monitoring including baseline and follow-up lipid evaluations is advised.
  - Clinically significant, sometimes very high, elevations in triglycerides and modest mean increases in total cholesterol have been observed with olanzapine use.

- **Weight**
  - Monitor patient weight regularly during treatment with olanzapine.
  - Consider potential consequences of weight gain prior to initiating olanzapine.

- Undesirable lipid alterations have been observed during treatment with olanzapine. Clinical monitoring, including baseline and follow-up lipid evaluations, is advised.
- Clinically significant and sometimes very high elevations in triglycerides have been observed during olanzapine use. Modest mean increases in total cholesterol have also been observed.
- Patients should be monitored regularly for weight gain during treatment with olanzapine. Prescribers should consider the potential consequences of weight gain prior to initiating treatment.
In premarketing clinical trials, an unexpected degree of delirium and/or sedation was reported in a small number of patients with schizophrenia shortly after receiving an injection. This event has been termed Post-injection Delirium/Sedation Syndrome, or PDSS.

Across all ZYPREXA RELPREVV premarketing clinical trials as of 18 June 2009, over 2000 patients have received over 50,000 injections of ZYPREXA RELPREVV. Of these, 0.07% of injections were followed by patients experiencing this temporary post-injection reaction. This incidence corresponds to 1 PDSS event occurring for approximately every 1400 injections. To put this rate into context, in a clinic with 60 patients given 1 injection every 2 weeks, you would expect to see approximately 1 such event per year.

Nevertheless, it is important to be aware that a PDSS event can occur in any patient at any injection.
What is Post-Injection Delirium/Sedation Syndrome?

- Appears related to excessive olanzapine plasma concentrations
- Presentation consistent with many symptoms of oral olanzapine overdose
- Most patients developed symptoms of:
  - Sedation, ranging from mild in severity up to coma (lasting up to 12 hrs) and/or
  - Delirium, including confusion, disorientation, agitation, anxiety and other cognitive impairment
  - Other symptoms noted included extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension or convulsions
- Typically began with milder symptoms which progress in severity and/or number
- Presentation can appear similar to alcohol intoxication

<table>
<thead>
<tr>
<th>Time of Onset of Symptoms</th>
<th>% of Patients*</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤1 hour</td>
<td>~80%</td>
</tr>
<tr>
<td>&gt;1 to 3 hours</td>
<td>~ 14%</td>
</tr>
<tr>
<td>&gt;3 hours</td>
<td>~ 6%</td>
</tr>
</tbody>
</table>

* As of 19 June 2009.
Data on file, Lilly Research Laboratories, ZYP30000200A

What is Post-injection Delirium/Sedation Syndrome?

- These events appear to be related to excessive olanzapine plasma concentrations and presentation of the events are consistent with many symptoms of oral olanzapine overdose. While the precise mechanism of these events remains unknown, ZYPREXA RELPREVV is more soluble in blood than in muscle. Contact with a substantial volume of blood would lead to faster dissolution (as the olanzapine disassociates from the pamoic acid), resulting in higher than expected olanzapine concentrations. There are several ways that such contact could occur, including direct or partial injection into the vasculature, blood vessel injury during the injection, or as the result of an extravascular bleed around the vessel.

- Most patients who experienced such an event developed symptoms related to sedation and/or delirium. Sedation could range from mild to severe, and in one case included coma lasting up to 12 hours. Symptoms related to delirium could include confusion, disorientation, agitation, anxiety, and other cognitive impairment. Other symptoms that were noted in some cases included extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension, or convulsions.

- PDSS events typically began with milder symptoms which then progressed in severity and/or number. The clinical presentation has sometimes been described as appearing similar to that of alcohol intoxication.

- Time after injection to event ranged from soon after injection to greater than 3 hours after injection.
There have been no clinically significant decreases in blood pressure and no respiratory depression noted in any of the PDSS events in the premarketing clinical trials. Approximately 15% of cases experienced temporary unconsciousness. In most cases, patients were hospitalized for further observation and/or treatment. Two patients were intubated prophylactically following parenteral administration of benzodiazepines, with no respiratory depression noted. Concomitant medications or substances have not been shown to be risk factors for these events.

It is important to note that all patients who experienced a post-injection syndrome event largely recovered within 72 hours. Time of full recovery has ranged from 1.5 to 72 hours, with full recovery defined as the absence of signs or symptoms of the event. Approximately 70% of these patients chose to continue receiving ZYPREXA RELPREVIV following the event.
## Safety Precautions at Every ZYPREXA RELPREVV Injection

- **Before the injection:**
  - For product reconstitution procedure, review the Reconstitution and Administration Poster and the Reconstitution and Administration Training video available on the ZYPREXA RELPREVV Patient Care Program Web site.
  - Provide the Medication Guide and answer patient or legal guardian questions prior to each injection.
  - **IMPORTANT:** Confirm there will be someone to accompany the patient after the 3-hour monitoring period. If this cannot be confirmed, do not give the injection.

Because there is a risk of a PDSS event with each injection, the following precautions should be followed every time a patient receives a ZYPREXA RELPREVV injection. For a description of the product reconstitution and administration procedures, please review the Reconstitution and Administration Poster and training video available on the ZYPREXA RELPREVV Patient Care Program web site.

The Medication Guide must be given to patients, their families or their caregivers prior to each injection. For additional information about ZYPREXA RELPREVV, patients can receive the patient education brochure, Getting Started with My Medicine. Prescribers or other healthcare professionals should instruct patients, their families, and their caregivers to read these documents and should assist them in understanding the contents. Before each injection, patients or legal guardian should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have.

Before administering ZYPREXA RELPREVV, confirm that the patient will be accompanied to their destination (for example to their home or workplace) when they leave the healthcare facility. If this cannot be confirmed, do not give the injection.
### Safety Precautions at Every ZYPREXA RELPREVV Injection

**During the injection:**

- ZYPREXA RELPREVV is intended for deep intramuscular gluteal injection only
  - Do not administer intravenously or subcutaneously
  - Not approved for deltoid injections
- Administrator must aspirate the syringe for several seconds prior to injection to ensure no blood is visible
- Do not proceed with injection if blood is visible in the syringe
  - Discard syringe and use a new vial
  - Reconstitute a new vial and inject into alternate side of buttock, deep into gluteal muscle

For complete safety profile, including boxed warnings, see the full Prescribing Information.

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It is important to note that the risk of a PDSS event is present with each injection of ZYPREXA RELPREVV. Although this risk cannot be eliminated, good injection technique is necessary to minimize the occurrence of these events.

ZYPREXA RELPREVV is intended for deep intramuscular gluteal injection only. Do not administer intravenously or subcutaneously. It is not approved for deltoid injections.

Administrators must aspirate the syringe for several seconds prior to injection to ensure that no blood is visible in the syringe. If blood is visible, they must not proceed with the injection. They should discard the syringe and reconstitute a new vial for injection, then inject into the alternate side of the buttock, deep into the gluteal muscle.
After the injection:

- A healthcare professional must continuously observe the patient at the registered healthcare facility with ready access to emergency response services for at least 3 hours
  - The patient should be located where he/she can be seen and/or heard
  - The 3-hour observation period may be used to conduct other activities, such as psychosocial and psychoeducational programs

Directly after the injection, patients must be observed by appropriately qualified personnel at the registered healthcare facility with ready access to emergency response services for at least 3 hours. The patient should be located in an area where he or she can be seen and/or heard at all times. The 3-hour observation period may be used to conduct other activities, such as psychosocial or psychoeducational programs.
Safety Precautions at Every ZYPREXA RELPREVV Injection

- **Before patient leaves the healthcare facility:**
  - Confirm that the patient is alert, oriented, and without signs or symptoms of a post-injection delirium/sedation syndrome event. If PDSS is suspected, close medical supervision and monitoring should be instituted in a facility capable of resuscitation.
  - Advise patients and caregivers to be vigilant for symptoms of a PDSS event for the remainder of the day and be able to obtain medical assistance if needed.
  - All patients must be accompanied to their destination upon leaving the facility.

- **After leaving the healthcare facility:**
  - For the remainder of the day of each injection, patients should not drive or operate heavy machinery.

After completion of the observation period and before the patient leaves the healthcare facility, the patient must be confirmed to be alert, oriented, without any signs or symptoms of a PDSS event. If PDSS is suspected, close medical supervision and monitoring should be instituted in a facility capable of resuscitation.

The patient and the caregiver should be advised to be vigilant for appearance of symptoms of a PDSS event for the remainder of the day and should be able to obtain medical assistance if needed. All patients must be accompanied to their destination upon leaving the facility.

Patients should also be cautioned that after leaving the facility, they should not drive or operate heavy machinery for the remainder of the day.
Clinical Management of PDSS Events

- Patients experiencing PDSS should be managed as clinically appropriate
  - If post-injection delirium/sedation syndrome is suspected, close medical supervision and monitoring should be instituted in a facility capable of resuscitation
  - Patients may be treated symptomatically
  - If parenteral benzodiazepines are required for patient management during a PDSS event, careful evaluation of clinical status for excessive sedation and cardiorespiratory depression is recommended
  - If the patient is sent to a hospital for further observation and/or management, it is recommended that the prescribing healthcare professional notify the hospital personnel that the patient is experiencing a probable olanzapine overdose following injection of ZYPREXA RELPREVV

  Report any suspected PDSS event within 24 hours through the ZYPREXA RELPREVV Patient Care Program

What should be done if a patient experiences a post-injection syndrome event?

- There is no specific antidote for olanzapine overdose. Patients experiencing PDSS should be managed as clinically appropriate and may be treated symptomatically in a facility capable of resuscitation.
- If parenteral benzodiazepines are required for patient management during a PDSS event, careful evaluation of clinical status for excessive sedation and cardiorespiratory depression is recommended.
- If the patient is sent to a hospital for further observation and/or management, it is recommended that the prescribing healthcare professional notify the hospital personnel that the patient is experiencing a probable olanzapine overdose following injection of ZYPREXA RELPREVV.
- It is very important that you report any suspected PDSS event through the ZYPREXA RELPREVV Patient Care Program within 24 hours of becoming aware of the event.
Clinical Management Following PDSS Events

Following a PDSS event

- If treatment with ZYPREXA RELPREVV is continued:
  - The next injection may occur as previously scheduled, or earlier if clinically indicated for exacerbation of symptoms
  - Temporary oral supplementation may be considered

- If ZYPREXA RELPREVV is discontinued:
  - The effects of ZYPREXA RELPREVV will continue for some time after discontinuation
  - Treatment with alternative medication may be started when clinically indicated

In clinical trials, after a PDSS event, approximately 70% of patients elected to continue to receive ZYPREXA RELPREVV and were dosed at their next regularly scheduled visit.

If the healthcare professional and patient decide to continue treatment with ZYPREXA RELPREVV following a PDSS event, the next injection may occur as previously scheduled. Dosing and/or oral supplementation should be managed as clinically indicated.

If ZYPREXA RELPREVV is discontinued following a PDSS event, the healthcare professional should be aware that, as with all long-acting medications, the effects of ZYPREXA RELPREVV will continue for some time after discontinuation of the drug. Treatment with alternative medication may be started when clinically indicated.
ZYPREXA RELPREVV is available only through a controlled distribution system to registered prescribers for use in registered facilities. Participation in the ZYPREXA RELPREVV Patient Care Program is mandatory for patients, prescribers, healthcare facilities and pharmacy service providers.

The goal of the ZYPREXA RELPREVV Patient Care Program is to mitigate the risk of negative outcomes associated with ZYPREXA RELPREVV post-injection delirium/sedation syndrome (PDSS) by:

- Ensuring ZYPREXA RELPREVV is prescribed only by certified prescribers, dispensed only by certified dispensers, and dispensed for use only in certified healthcare facilities with ready access to emergency response services, and dispensed for use only with documentation of safe use conditions;
- Informing health care providers and patients about the risks and the need for continuous observation of patients for at least 3 hours in certified healthcare facilities; and
- Establishing long-term safety and safe use of ZYPREXA RELPREVV through periodic monitoring for the risk of PDSS events and by enrolling all patients who receive ZYPREXA RELPREVV in the ZYPREXA RELPREVV Patient Care Program registry.
Required Enrollments

- In order to use ZYPREXA RELPREVV, all of the following must be enrolled in the ZYPREXA RELPREVV Patient Care Program:
  - Prescriber
  - Healthcare facility or program
  - Patient
  - Pharmacy service provider
- Only patients who are enrolled in the ZYPREXA RELPREVV Patient Care Program may receive ZYPREXA RELPREVV injections

For detailed enrollment information, refer to the ZYPREXA RELPREVV Patient Care Program Website at www.zyppexarelprevprogram.com or call 877-772-9390

Much like other programs, enrollment is required for the prescriber, patient, and pharmacy.

In addition, a unique component of the ZYPREXA RELPREVV Patient Care Program is that the healthcare facility or program will also be required to be enrolled in the ZYPREXA RELPREVV Patient Care Program. These requirements will be described next.

Detailed information on all required enrollments is available by accessing the ZYPREXA RELPREVV Patient Care Program Web site or calling 877-772-9390.
Prescriber Registration

All prescribers who intend to prescribe ZYPREXA RELPREVV must enroll in the ZYPREXA RELPREVV Patient Care Program prior to treating any patient with ZYPREXA RELPREVV.

Prescriber obligations include:

- Completing the mandatory ZYPREXA RELPREVV training
- Understanding the ZYPREXA RELPREVV Patient Care Program requirements and the risks associated with ZYPREXA RELPREVV
- Understanding the clinical presentation of PDSS and how to manage patients should an event occur while using ZYPREXA RELPREVV
- Understanding that ZYPREXA RELPREVV should only be administered to patients in healthcare settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection
- Initiating ZYPREXA RELPREVV only in patients for whom tolerability with oral olanzapine has been established
- Reviewing the ZYPREXA RELPREVV Medication Guide with each patient or legal guardian prior to prescribing
- Ensuring that all patients are enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to prescribing ZYPREXA RELPREVV by completing the Patient Registration Form
- Ensuring all suspected cases of PDSS are reported to the ZYPREXA RELPREVV Patient Care Program within 24 hours of becoming aware of the event
- Agreeing to be contacted by the ZYPREXA RELPREVV Patient Care Program coordinating center to resolve discrepancies, to obtain information about a patient, or to conduct occasional surveys

For complete safety profile, including boxed warnings, see the full Prescribing Information.
All patients who are treated with ZYPREXA RELPREVV must be enrolled in the ZYPREXA RELPREVV Patient Care Program prior to receiving their first ZYPREXA RELPREVV injections.

- Enrollment includes signed patient attestation of understanding of the ZYPREXA RELPREVV Patient Care Program data collection requirements, ZYPREXA RELPREVV’s risks and benefits, and the special precautions which safe use of the product mandate.
- If a patient is unable to provide attestation, his/her legal guardian will consult with the prescriber and provide attestation for the patient.
- In situations where a patient is under a court order for involuntary psychiatric treatment which permits administration of medications without patient consent, patient signature can be omitted. However, check the appropriate box and provide the expiration date for the Court Order.

All patients who are treated ZYPREXA RELPREVV must be enrolled in the ZYPREXA RELPREVV Patient Care Program prior to receiving their first ZYPREXA RELPREVV injection.

- Enrollment includes signed patient attestation of understanding of the ZYPREXA RELPREVV Patient Care Program data collection requirements, ZYPREXA RELPREVV’s risks and benefits, and the special precautions mandated for safe use of the product.
- If a patient is unable to provide attestation, his/her legal guardian will consult with the prescriber and provide attestation for the patient.
- In situations where a patient is under a court order for involuntary psychiatric treatment which permits administration of medications without patient consent, patient signature can be omitted. However, check the appropriate box and provide the expiration date for the Court Order.
The healthcare facility where a patient will receive the injection of ZYPREXA RELPREVV must also enroll in the ZYPREXA RELPREVV Patient Care Program prior to any patients being enrolled.

Healthcare facility obligations include:

- Ensuring that all appropriate staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure as well as the Training Materials
- Ensuring that all appropriate staff understand that ZYPREXA RELPREVV can only be dispensed for use in certain healthcare settings (e.g., hospitals, clinics) that have ready access to emergency response services that can allow for continuous patient monitoring for at least 3 hours post-injection
- Ensuring the facility has systems, protocols, or other measures to ensure that ZYPREXA RELPREVV is only administered to patients enrolled in the program, and that patients are continuously monitored for at least 3 hours post-injection for suspected PDSS
- Ensuring that appropriate staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to each injection by accessing the system
- Ensuring that the Medication Guide is provided to the patient or legal guardian prior to each injection
- Ensuring that the appropriate staff monitors the patient continuously for at least 3 hours
- Ensuring that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVV Patient Care Program
- Understanding the facility may be contacted by the ZYPREXA RELPREVV Patient Care Program Coordinating Center to clarify information provided or obtain information about the patient

For complete safety profile, including boxed warnings, see the full Prescribing Information.
Pharmacy Service Provider Registration

All pharmacy service providers that intend to order and dispense ZYPREXA RELPREVX must enroll in the ZYPREXA RELPREVX Patient Care Program and agree to comply with the program including data collection, confirmation of eligible prescribers and patients prior to dispensing, and program reporting requirements.

- Pharmacy Service Provider obligations include:
  - Ensuring that all appropriate pharmacy staff are trained and have read and understand the ZYPREXA RELPREVX Patient Care Program Instructions Brochure
  - Ensuring that all appropriate pharmacy staff understand that ZYPREXA RELPREVX can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services that can allow for continuous patient monitoring for at least 3 hours post-injection
  - Ensuring that pharmacy staff will verify that the patient is enrolled in the ZYPREXA RELPREVX Patient Care Program registry prior to dispensing each prescription/refill by accessing the system
  - Ensuring that pharmacy staff will not dispense ZYPREXA RELPREVX directly to patients
  - Ensuring that pharmacy staff report the date of each ZYPREXA RELPREVX dispensing to the ZYPREXA RELPREVX Patient Care Program
  - Understanding that the pharmacy may be contacted by the ZYPREXA RELPREVX Patient Care Program to clarify information provided or to obtain information about a patient

For complete safety profile, including boxed warnings, see the full Prescribing Information.

Reference ID: 4417451
After this training, you should now be able to:

- Differentiate between ZYPREXA RELPREVV (olanzapine for extended release injectable suspension) and ZYPREXA IntraMuscular (olanzapine for injection) to avoid medication errors.
- Understand the dosing options with ZYPREXA RELPREVV.
- Know the common adverse events associated with ZYPREXA RELPREVV and how to monitor patients for metabolic changes.
- Identify a post-injection delirium/sedation syndrome (PDSS) event in your clinical practice.
- Know the conditions of safe use and how to manage the risk of PDSS.
- Know what to do in case a PDSS event occurs.
- Understand basics of the ZYPREXA RELPREVV Patient Care Program.

For complete safety profile, including boxed warnings, see the full Prescribing Information.
ZYPREXA RELPREVV (olanzapine) For Extended Release Injectable Suspension

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVV, including Boxed Warnings.
Enclosed Registration Forms Include:

► Prescriber Registration
   Enrolls the prescriber to treat patients with ZYPREXA RELPREVV.

► Pharmacy Service Providers
  ▪ Pharmacy Registration
    Enrolls the pharmacy to order and dispense ZYPREXA RELPREVV.
  ▪ Buy and Bill Pharmacy Service Provider Registration
    For prescribers who get product through standard buy and bill procedures, this form enrolls the prescriber
    as a Pharmacy Service Provider. **NOTE: Prescribers intending to buy and bill must complete both the Prescriber and Buy and Bill Pharmacy Service Provider Registration Forms.**

► Patient Registration
  Enrolls the patient to receive treatment with ZYPREXA RELPREVV.

► Patient Registration Form – Patient Copy
  Provides patient or caregiver a copy of attestations from the Patient Registration Form.

► Healthcare Facility Registration
  Enrolls the healthcare facility to administer ZYPREXA RELPREVV injections and monitor patients after
  each injection.
ZYPREXA RELPREVV Prescribing Information and Medication Guide
Patient Injection and PDSS Reporting Forms

**Single Patient Injection Form**
- Used to collect the data for a single patient after treatment administration of ZYPREXA RELPREVV.
- This form is to be sent to the ZYPREXA RELPREVV Patient Care Program Coordinating Center within 7 days after the patient’s injection.

**Multiple Patient Injection Form**
- Used when injections are administered to multiple patients on the same day at a given facility.
  - This form is used to collect the data for multiple patients after treatment administration of ZYPREXA RELPREVV.
- This form is to be sent to the ZYPREXA RELPREVV Patient Care Program Coordinating Center within 7 days after the patients’ injections.

Patient injection data should only be completed either via the Single Patient Injection Form or the Multiple Patient Injection Form. Do not use both forms for an individual injection; this will result in duplicate reporting.

**Post-Injection Delirium/Sedation Syndrome (PDSS) Form**
- This form is used to collect the required data when a suspected PDSS event occurs after administration of ZYPREXA RELPREVV, either during the 3-hour observation period or any time thereafter. This form must be provided to the ZYPREXA RELPREVV Patient Care Program Coordinating Center within 24 hours of becoming aware of a suspected PDSS event.
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Introduction to the
ZYPREXA RELPREVV Patient Care Program

Patient Care Program Overview
ZYPREXA RELPREVV is the long-acting intramuscular formulation of olanzapine indicated for treatment of schizophrenia. The ZYPREXA RELPREVV Patient Care Program is a Risk Evaluation and Mitigation Strategy (REMS) program necessary to mitigate the risk of negative outcomes associated with ZYPREXA RELPREVV post-injection delirium/sedation syndrome (PDSS). In order to prescribe, dispense, receive, or administer ZYPREXA RELPREVV, healthcare professionals need to:

- Enroll in the ZYPREXA RELPREVV Patient Care Program
- Ensure the collection of information for each injection of ZYPREXA RELPREVV

Post-Injection Delirium/Sedation Syndrome:
ZYPREXA RELPREVV has been associated with a post-injection delirium/sedation syndrome characterized primarily by signs and symptoms consistent with olanzapine overdose. This syndrome does not apply to any other formulation of olanzapine, including ZYPREXA IntraMuscular (olanzapine for injection). The prescribing information for ZYPREXA RELPREVV includes the following BOXED WARNING.

BOXED WARNING
See full prescribing information and the healthcare professional training for complete information on PDSS.

Post-Injection Delirium/Sedation Syndrome — Adverse events with signs and symptoms consistent with olanzapine overdose, in particular, sedation (including coma) and/or delirium, have been reported following injections of ZYPREXA RELPREVV. ZYPREXA RELPREVV must be administered in a registered healthcare facility with ready access to emergency response services. After each injection, patients must be observed at the healthcare facility by a healthcare professional for at least 3 hours. Because of this risk, ZYPREXA RELPREVV is available only through a restricted distribution program called ZYPREXA RELPREVV Patient Care Program and requires prescriber, healthcare facility, patient, and pharmacy enrollment.

Increased Mortality in Elderly Patients with Dementia-Related Psychosis — Elderly patients with dementia related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. ZYPREXA RELPREVV is not approved for the treatment of patients with dementia-related psychosis.
ZYPREXA RELPREVV Patient Care Program Enrollment

**Prescriber**
- Reviews educational materials
- Submits enrollment form to ZYPREXA RELPREVV Patient Care Program Coordinating Center

**Healthcare Facility**
- Ensures staff are trained and facility can comply with conditions of safe use
- Submits enrollment form to ZYPREXA RELPREVV Patient Care Program Coordinating Center
- Receives & stores patient authorization notification

**Patient**
To enroll patient, prescriber:
-Reviews risks of ZYPREXA RELPREVV with patient
-Obtains signature of patient or legal guardian OR check box if court order of involuntary commitment
-Submits enrollment form to ZYPREXA RELPREVV Patient Care Program Coordinating Center
- Receives & stores patient authorization notification

**Pharmacy Service Provider**
- Reviews ZYPREXA RELPREVV Patient Care Program materials
- Ensures pharmacy staff are trained
- Submits enrollment form to ZYPREXA RELPREVV Patient Care Program Coordinating Center

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ZYPREXA RELPREVV Patient Care Program Process Flow

**Ordering**
- Enrolled Pharmacy Service Provider places ZYPREXA RELPREVV order with regular wholesaler

**ZYPREXA RELPREVV Patient Care Program Database and Coordinating Center**

**Pharmacy Service Provider**
- Receives ZYPREXA RELPREVV

**Order is forwarded to Lilly/Specialty Distributor**
- Lilly/Specialty Distributor verifies Pharmacy Service Provider eligibility via the on-line system

**Patient eligibility is confirmed**, Lilly/Specialty Distributor ships # units ordered of ZYPREXA RELPREVV

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**Dispensing**
- Prescriber submits prescription and patient identification number (PIN) to Pharmacy Service Provider*
- Pharmacy Service Provider confirms patient eligibility via the on-line system or via the Interactive Voice Response System (IVRS)
- Patient eligibility is confirmed*
- Pharmacy Service Provider dispenses ZYPREXA RELPREVV to registered healthcare facility as indicated by the on-line system or IVRS and enters dispense date via the on-line system or via IVRS.

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**Treatment**
- Healthcare Professional/Prescriber
  - administers ZYPREXA RELPREVV
  - observes patient for 3 hours
  - reports data* for every injection and suspected PDSS event to the ZYPREXA RELPREVV Patient Care Program

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**Key**
- Prescriber Activities
- Healthcare Facility Activities
- Pharmacy Service Provider Activities

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*For the first prescription include the patient authorization notification

*If patient is not eligible, contact the ZYPREXA RELPREVV Patient Care Program Coordinating Center

*Data entry is required for patient to be eligible for refill

*PDSS = post-injection delirium/sedation syndrome
For questions regarding the Patient Care Program or to enroll, please contact the Patient Care Program Coordinating Center:

**Via Telephone:** 1-877-772-9390  
Monday – Friday: 8:00am – 8:00pm ET

**Via Mail:** ZYPREXA RELPREVV Patient Care Program  
P.O. Box 4649  
Star City, WV 26504-4649

**Via Fax:** 1-877-772-9391

**Via Internet:** www.zyprexarelprevvprogram.com
Prescriber Information

Prescribers must enroll in the ZYPREXA RELPERV Patient Care Program in order to prescribe ZYPREXA RELPERV.

Enrolling in the ZYPREXA RELPERV Patient Care Program will allow prescribers to securely and easily view data for all of the patients they have enrolled in the program, along with the patients' next expected injection dates and injection histories.

Upon registration, the prescriber will be sent a username and password, which allows secured access to the on-line Patient Care Program system. The prescriber is responsible for entering required Patient Care Program data for any PDSS event that occurs.

Prescribers who obtain ZYPREXA RELPERV through a pharmacy: Provide a prescription to a registered pharmacy.

Prescribers who order and dispense ZYPREXA RELPERV through bill and bill procedures: Enroll as a Buy and Bill Pharmacy Service Provider as described on pages 9 and 10 of this brochure.

The facility/practice where injections are administered or patients are monitored must be enrolled in the ZYPREXA RELPERV Patient Care Program as a healthcare facility as described on page 7. The Prescriber will receive an email or fax notification once the healthcare facility(s) become enrolled. The healthcare facility(s) are required to enter data following each patient injection.

Three Steps to Prescriber Enrollment:

1. **Review:**
   Attend a training or review the following educational materials:
   - ZYPREXA RELPERV Patient Care Program Instructions Brochure (this document)
   - Healthcare Professional Training Slide Presentation with text notes or Recorded Presentation with participant guide, available at www.zyprexa-relprevprogram.com

2. **Complete/Sign:**
   Complete the Prescriber Registration Form on-line, or print and sign.

3. **Submit:**
   Submit on-line or via fax or mail to the Patient Care Program Coordinating Center.

Prescribers must repeat the enrollment process every 3 years. You will be notified by fax or email 60 days prior to your reenrollment date.
Prescriber Information

To report SUSPECTED ADVERSE REACTIONS other than PDSS, contact Eli Lilly and Company at 1-800-LILLYRX (1-800-545-5979) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

The prescriber is responsible for enrolling the patient in the ZYPREXA RELPREVVC Patient Care Program prior to writing a prescription for that patient.

Three Steps to Patient Enrollment:

1. Confirm:
   • Both the prescriber and the healthcare facility where the patient will receive the injection are enrolled in the ZYPREXA RELPREVVC Patient Care Program.
   • Patient has been provided with a Medication Guide and informed about the risks associated with the administration of ZYPREXA RELPREVVC.
   • Patient has been informed about the Patient Care Program guidelines.

2. Complete/Sign:
   Complete a Patient Registration Form and have the patient or legal guardian sign the form, or check the box relating to the presence of a court order. If the court order box is checked, provide the expiration date of the court order. Provide the Patient Registration Form—Patient Copy version to the patient or legal guardian.

3. Submit:
   Submit on-line or via fax or mail to the Patient Care Program Coordinating Center.

After enrollment is complete, a unique Patient Identification Number (PIN) and a healthcare facility unique identifier will be provided to the prescriber via a patient authorization notification fax or email.

The prescriber should provide the patient’s PIN and healthcare facility unique identifier with the first prescription to assist the pharmacy service provider in completing its ZYPREXA RELPREVVC Patient Care Program responsibilities.

For any changes in patient care setting, changes in prescriber, or to discontinue or reactivate a patient, call the Coordinating Center (1-877-772-9390).

Patient Care Program Data Entry
All suspected cases of PDSS should be reported to the ZYPREXA RELPREVVC Patient Care Program within 24 hours of awareness of the event. The ZYPREXA RELPREVVC Patient Care Program may need to contact you to obtain additional information to further characterize the PDSS event.

For each suspected PDSS event, the prescriber can record and submit data to the Patient Care Program in one of the following ways:

Via Telephone: 1-877-772-9390
Via Fax: 1-877-772-9391
Via Internet: www.zyprexarelprevvcprogram.com

Steps for On-line Data Entry

1. With the assigned username and password, log in to the ZYPREXA RELPREVVC Patient Care Program system through the website.

2. Upon logging into the Patient Care Program system, the prescriber will see only their associated patients and the option to enroll new patients.

3. Select:
   • The appropriate patient for whom he/she is entering data.
   • Or the option to enroll a new patient.

4. The system will prompt the prescriber to enter enrollment data for a new patient, or PDSS data for an already enrolled patient.
A healthcare facility must be enrolled in the ZYPREXA RELPREVV Patient Care Program to: ensure each patient is enrolled in the Patient Care Program prior to administering an injection, to administer ZYPREXA RELPREVV and/or to monitor patients who have been administered ZYPREXA RELPREVV and to enter data for each injection administered to a patient.

**Authorized Healthcare Facility Representative**

The authorized healthcare facility representative must ensure that all appropriate staff responsible for administering ZYPREXA RELPREVV and for monitoring patients are educated on ZYPREXA RELPREVV injection techniques, signs and symptoms of PDSS, and patient monitoring requirements following injection. Additionally, the authorized healthcare facility representative is responsible to ensure systems are in place to report all PDSS events to the prescriber and to identify all appropriate staff as delegates who will be responsible for entering data following each injection.

**Patient Care Program Data Entry**

The authorized healthcare facility representative may assign the Patient Care Program responsibilities to a delegate(s). Upon registration, the delegate(s) will be sent a username and password, which allows secured access to the on-line Patient Care Program system. After registration, additional delegates may be assigned by calling the Coordinating Center (1-877-772-9390).

---

### Three Steps to Healthcare Facility Enrollment:

1. **Review:**
   Staff involved with ZYPREXA RELPREVV patients review the educational materials listed below. Materials are available on-line, through an on-line order form, or by calling the ZYPREXA RELPREVV Patient Care Program Coordinating Center.
   - Required for nurse or other individuals giving injections:
     - ZYPREXA RELPREVV Patient Care Program Instructions Brochure (this document)
     - Healthcare Professional Training Slide Presentation with text notes or Recorded Presentation
     - ZYPREXA RELPREVV Patient Care Program Instructions Brochure (this document)
   - Required for staff working with patients post-injection:
     - Healthcare Professional Training Slide Presentation with text notes or Recorded Presentation

2. **Complete/Sign:**
   Healthcare facility representative completes the Healthcare Registration Form on-line or print and sign.

3. **Submit:**
   Submit on-line or via fax or mail to the ZYPREXA RELPREVV Patient Care Program Coordinating Center.

Healthcare facilities must repeat the enrollment process every 3 years. You will be notified by fax or email 60 days prior to your reenrollment date.
Healthcare Facility Information

After a patient associated with your facility is enrolled by a prescriber, a unique Patient Identification Number (PIN) will be assigned to the patient and provided to the facility via a patient authorization notification fax or email, which should be filed in the patient’s chart.

Prior to each injection, verify that the patient is enrolled in the Zyprexa Relprevv Patient Care Program registry by accessing the system.

Following the injection, patients are to be monitored continuously for at least 3 hours. Report required Patient Care Program injection data (see Injection Form) **within 7 days of injection administration.**

Injection data may be submitted individually for each patient by using the Single Patient Injection Form or for multiple patients by using the Multiple Patient Injection Form.

For each injection, record and submit injection data to the Patient Care Program in one of the following ways:

**Via Telephone:** 1-877-772-9390  
**Via Fax:** 1-877-772-9391  
**Via Internet:** www.zyprexarelprevvprogram.com

**Steps for On-line Data Entry**

1. With the assigned username and password, log in to the ZYPREXA RELPREVV Patient Care Program system through the website.

2. Upon logging into the Patient Care Program system, the delegate will see only their associated patients.

3. Select the appropriate patient and dispense date to enter injection data.

4. The system will prompt the delegate to enter injection data for an enrolled patient.

**Product Replacement**

If, during the course of reconstitution or administration of ZYPREXA RELPREVV, the medication becomes unusable (e.g., aspiration of blood or a broken vial), call the Coordinating Center.
Pharmacy Service Provider Information

A pharmacy service provider must be enrolled in the ZYPREXA RELPREVV Patient Care Program to order and dispense ZYPREXA RELPREVV. Pharmacy service providers include any retail pharmacy, hospital pharmacy, physician or healthcare facility that can order and dispense ZYPREXA RELPREVV.

Three Steps to Pharmacy Service Provider Enrollment:

1. **Review:**
   Pharmacy staff should review the training and education material within this document before dispensing the medication.

2. **Complete:**
   Representative for the pharmacy service provider completes a registration form, depending upon the type of pharmacy operation.
   - Pharmacy Registration Form: Enrolls a pharmacy to allow ordering and dispensing of ZYPREXA RELPREVV. To be completed by the pharmacist in charge.
   - Buy and Bill Pharmacy Service Provider Registration Form: Enrolls a prescriber organization that wishes to order and dispense ZYPREXA RELPREVV to patients through buy and bill procedures.

3. **Submit:**
   Submit on-line or via fax or mail to the ZYPREXA RELPREVV Patient Care Program Coordinating Center.

   Pharmacy Service Providers must repeat the enrollment process every 3 years. You will be notified by fax or email 60 days prior to your reenrollment date.

Ordering ZYPREXA RELPREVV

ZYPREXA RELPREVV will be shipped through a controlled distribution system. Following the pharmacy service provider registration, the Patient Care Program Coordinating Center will notify distributors that the pharmacy is enrolled. The pharmacy will then be able to submit orders for ZYPREXA RELPREVV to their regular wholesaler.

Patient Care Program requirements must be followed for the pharmacy to maintain an active registration status and to have continued access to ZYPREXA RELPREVV.

Dispensing ZYPREXA RELPREVV

It is the responsibility of the pharmacy service provider to verify the ongoing eligibility of the patient prior to dispensing each prescription and entering the date of each dispensing. The pharmacist will ensure prescription verification (including patient eligibility check and recording the dispense date) is completed on the date of dispense, prior to the vial kit leaving the pharmacy. This is accomplished by contacting the Patient Care Program in one of the following ways:

- **Via Telephone/IVRS:** 1-877-772-9390
- **Via Internet:** www.zyrexarelpervvprogram.com

Prior to dispensing ZYPREXA RELPREVV, the pharmacy service provider must confirm that the prescriber, healthcare facility, and patient are enrolled in the ZYPREXA RELPREVV Patient Care Program and that the patient is eligible to receive ZYPREXA RELPREVV via the process outlined below. **The pharmacy service provider must only dispense ZYPREXA RELPREVV to registered healthcare facilities or a healthcare professional, not directly to a patient.**

A patient identification number (PIN) and healthcare facility unique identifier should be provided by the prescriber with the first prescription. Through the on-line Patient Care Program system, the PIN will quickly identify the patient and prescriber as enrolled in the Patient Care Program. The healthcare facility unique identifier will allow confirmation of healthcare facility registration. The system will indicate the patient's eligibility to receive a dispensing of ZYPREXA RELPREVV.
Patient eligibility is determined by enrollment in the Patient Care Program and entry of required injection data into the Patient Care Program system by the healthcare facility.

**Steps to Dispense:**

1. Order the product from a distributor.

2. Receive ZYPREXA RELPREVV from distributor and maintain a supply of product at the pharmacy.

3. Receive a valid prescription, patient identification number (PIN), and healthcare facility unique identifier.

4. Maintain the PIN and healthcare facility unique identifier in the patient record within the pharmacy system to access when refilling a prescription.

5. With the assigned username and password, access the ZYPREXA RELPREVV Patient Care Program system in one of three ways: access the website or call the Coordinating Center (1-877-772-9390) and chose either the Interactive Voice Response System (IVRS) option or speak to a Patient Care Program representative.

**Web based – www.zyprexarelprevvprogram.com**

- Enter the PIN (If the PIN is not provided, call the Coordinating Center and provide patient’s first and last name, patient’s date of birth and prescriber’s name).
- System displays prescriber and patient name
- Confirm both names match prescription
- System displays healthcare facility number and name
- Confirm healthcare facility name/unique identifier matches patient authorization notification
- The system will indicate the patient’s eligibility to receive ZYPREXA RELPREVV.

- If eligible, the pharmacist will enter the date of dispensing (prior to the vial kit leaving the pharmacy) into the Patient Care Program system and dispense only to the healthcare facility (representative) associated with that patient. Do NOT dispense directly to a patient.
- If ineligible, do NOT dispense product. Contact the Patient Care Program Coordinating Center for resolution.

**Interactive Voice Response System – call 1-877-772-9390**

- Enter the PIN (If the PIN is not provided, call the Coordinating Center and provide patient’s first and last name, patient’s date of birth and prescriber’s name).
- IVRS provides first 5 letters of prescriber and patient last name
- Confirm both names match prescription
- IVRS provides healthcare facility unique identifier
- Confirm unique identifier/healthcare facility name matches patient authorization notification
- The system will indicate the patient’s eligibility to receive ZYPREXA RELPREVV.

- If eligible, the pharmacist will enter the date of dispensing (prior to the vial kit leaving the pharmacy) into the Patient Care Program system and dispense only to the healthcare facility (representative) associated with that patient. Do NOT dispense directly to a patient.
- If ineligible, do NOT dispense product. Contact the Patient Care Program Coordinating Center for resolution.
Call the Coordinating Center Help Desk
1-877-772-9390

- Provide the PIN (If the PIN is not available, provide patient’s first and last name, patient’s date of birth and prescriber’s name).

- Patient Care Program representative will ask pharmacy provider questions and provides verification of patient eligibility to receive ZYPREXA RELPREVV.

- If eligible, Patient Care Program representative will enter the date of dispensing prior to the vial kit leaving the pharmacy.

- Pharmacy Service Provider agrees to dispense only to the healthcare facility (representative) associated with that patient and not directly to a patient.

- If ineligible, Do NOT dispense product. The Coordinating Center will work to resolve.

Product Replacement
If, during the course of administering a ZYPREXA RELPREVV injection to a patient, an accident occurs that causes the ZYPREXA RELPREVV vial to be broken or to become unusable (e.g., aspiration of blood), call the Coordinating Center.

Reconciliation
Shipping records will be monitored against dispensing data by the Patient Care Program. If dispensing data are not provided, the pharmacy service provider will be contacted to obtain the information. Unreconciled discrepancies may lead to removal of the pharmacy from the approved list of pharmacies for ZYPREXA RELPREVV.
**Glossary of Terms**

**Healthcare Facility**
A healthcare facility administering and/or monitoring injections of ZYPREXA RELPREVV.

**Interactive Voice Response System (IVRS)**
System that allows a pharmacy service provider to confirm patient and prescriber eligibility and provide dispensing data via telephone rather than the on-line system.

**Patient Authorization Notification**
Provided to the prescriber and healthcare facility upon registration and includes the PIN and healthcare facility unique identifier. To be provided to the pharmacy service provider with the first prescription for each patient.

**Patient Identification Numbers (PIN)**
Unique numbers assigned to patients, which are used by the pharmacy service provider to confirm enrollment in the ZYPREXA RELPREVV Patient Care Program.

**Pharmacy Service Provider**
Any retail pharmacy, hospital pharmacy, physician, or properly licensed healthcare facility that can order for and deliver ZYPREXA RELPREVV to a healthcare professional in accordance with their agreement to implement all relevant requirements of the ZYPREXA RELPREVV Patient Care Program.

- Pharmacy - Retail and hospital pharmacies
- Buy & Bill Pharmacy Service Provider – a licensed healthcare provider that purchases pharmaceuticals through a licensed distributor for its own use in the treatment of a patient and then includes the cost of the pharmaceutical in its billing of patients and third-party payers.

**Post-Injection Delirium/Sedation Syndrome (PDSS)**
During premarketing clinical studies, adverse events that presented with signs and symptoms consistent with olanzapine overdose, in particular, sedation (including coma) and/or delirium, were reported in patients following an injection of ZYPREXA RELPREVV. Sedation ranged from mild in severity to coma and delirium included confusion, disorientation, agitation, anxiety, and other cognitive impairment. Other symptoms noted include extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension, and convulsion. The potential for onset of the event is greatest within the first hour. The majority of cases have occurred within the first 3 hours after injection; however, the event has occurred after 3 hours.

**Prescriber**
A healthcare professional writing prescriptions for ZYPREXA RELPREVV. Prescribers are responsible for ensuring that all patients receiving ZYPREXA RELPREVV are enrolled in the program.
BUY & BILL* PHARMACY SERVICE PROVIDER REGISTRATION FORM

To be enrolled in the ZYPREXA RELPREVV Patient Care Program, complete and fax this form to 1-877-772-9391.

Training must be completed before a pharmacy service provider may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

PHARMACY SERVICE PROVIDER INFORMATION

☐ Enrollment  ☐ Reenrollment

Facility Name: ____________________________

DEA Number: ____________________________

Please specify description of Pharmacy:  ☐ Community/Retail  ☐ Specialty Pharmacy  ☐ Hospital or Institution  ☐ Other

Address Line 1: ____________________________

Address Line 2: ____________________________

City: ____________________________ State: ____________ Zip: ____________

Primary Phone: ____________________________ Secondary Phone: ____________________________

Fax: ____________________________

SHIP TO INFORMATION

Ship To Address (if the same as above, check here)  ☐

Ship To Contact Name: ____________________________

Address Line 1: ____________________________

Address Line 2: ____________________________

City: ____________________________ State: ____________ Zip: ____________

Primary Phone: ____________________________ Secondary Phone: ____________________________

Fax: ____________________________

ADMINISTRATOR INFORMATION

First Name: ____________________________ Mi: ______ Last Name: ____________________________

Preferred Method of Communication:  ☐ Email  ☐ Fax

Email: ____________________________

Phone: ____________________________

Fax: ____________________________

(If different from above)

(If different from above)

PHARMACY SERVICE PROVIDER AGREEMENT

By signing below, I acknowledge that:

• I have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.
• I will ensure that all appropriate pharmacy staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.
• I will ensure that all appropriate pharmacy staff understand that ZYPREXA RELPREVV can only be dispensed for use in certain healthcare settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.
• I will ensure that pharmacy staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program prior to dispensing each prescription/retail by accessing the system.
• I will ensure that pharmacy staff will not dispense ZYPREXA RELPREVV directly to patients.
• I will ensure pharmacy staff report the date of each ZYPREXA RELPREVV dispensing to the ZYPREXA RELPREVV Patient Care Program.
• For each dispense I will ensure prescription verification (includes patient eligibility check and recording the dispense date) is completed on the date of dispense, prior to the vial kit leaving the pharmacy.
• I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the pharmacy to clarify information provided or to obtain information about the patient.

I may cancel this registration by notifying the ZYPREXA RELPREVV Patient Care Program Coordinating Center by fax at 1-877-772-9391 or by phone at 1-877-772-9390. If I cancel, Lilly will cease to supply ZYPREXA RELPREVV to the facility.

Administrator Signature: ____________________________

Date: ____________________________

Administrator Signature: ____________________________

Date: ____________________________

---

*Buy & Bill Pharmacy Service Provider - a licensed healthcare provider that purchases pharmaceuticals through a licensed distributor for its own use in the treatment of a patient and then includes the cost of the pharmaceutical in its billing of patients and third-party payers.

PHONE 1-877-772-9390  FAX 1-877-772-9391  www.zyprexaarlpervprogram.com

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Lilly
HEALTHCARE FACILITY INFORMATION

☐ Enrollment  ☐ Reenrollment

Healthcare Facility Name: ___________________________

Please specify location of Healthcare Facilities:  ☐ Prescriber Office  ☐ Clinic/Outpatient Facility  ☐ Hospital  ☐ Other

Address: __________________________________________

City: __________________________ State: ___________ Zip: ___________

Phone: __________________________ Fax: __________________________

AUTHORIZED HEALTHCARE FACILITY REPRESENTATIVE INFORMATION

First Name: __________________________ Mi: ______ Last Name: __________________________

Position/Title: __________________________

Phone: __________________________ Fax: __________________________

Email: __________________________

Preferred Method of Communication:  ☐ Email  ☐ Fax

You may identify Delegate(s) to enter the necessary patient data into the Patient Care Program system.

Delegate First Name: __________________________ Mi: ______ Last Name: __________________________

Facility Name: __________________________

Phone: __________________________ Fax: __________________________

Email: __________________________

Delegate First Name: __________________________ Mi: ______ Last Name: __________________________

Facility Name: __________________________

Phone: __________________________ Fax: __________________________

Email: __________________________

Delegate First Name: __________________________ Mi: ______ Last Name: __________________________

Facility Name: __________________________

Phone: __________________________ Fax: __________________________

Email: __________________________

Delegate First Name: __________________________ Mi: ______ Last Name: __________________________

Facility Name: __________________________

Phone: __________________________ Fax: __________________________

Email: __________________________

If additional Delegates are required contact the Patient Care Program Coordinating Center.

PHONE 1-877-772-9390  FAX 1-877-772-9391  www.zyprexarelprevprogram.com

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Reference ID: 4417451
HEALTHCARE FACILITY AGREEMENT

As the authorized representative for this facility, I attest that:

- I have read and understand the ZYPREXA RELPREVY Patient Care Program Instructions Brochure;
- I will ensure that all appropriate staff are trained and have read and understand the ZYPREXA RELPREVY Patient Care Program Instructions Brochure as well as the following Training Materials:
  - ZYPREXA RELPREVY Healthcare Professional Training
  - ZYPREXA RELPREVY Reconstitution and Administration Training
- I will ensure that all appropriate staff understand that ZYPREXA RELPREVY can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection;
- I will ensure the health care setting has systems, protocols, or other measures to ensure that ZYPREXA RELPREVY is only administered to patients enrolled in the program and that patients are continuously monitored for at least 3 hours post-injection for suspected PDSS;
- I will ensure that appropriate staff will verify that the patient is enrolled in the ZYPREXA RELPREVY Patient Care Program registry prior to each injection, by accessing the system;
- I will ensure that the Medication Guide is provided to the patient or the patient's legal guardian prior to each injection;
- I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours;
- I will ensure that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVY Patient Care Program.
- I understand that the ZYPREXA RELPREVY Patient Care Program Coordinating Center may contact the health care setting to clarify information provided or to obtain information about the patient.

I confirm that the information above is correct.

I understand that this information will be used to document healthcare facilities that are eligible to administer ZYPREXA RELPREVY.

I also understand that this information may be shared with government agencies.

I understand that Lilly will regularly evaluate ZYPREXA RELPREVY Patient Care Program compliance to ensure that program objectives are met. Lilly reserves the right to terminate a healthcare facility's enrollment at any time based upon non-compliance or to take other appropriate measures to assure that the ZYPREXA RELPREVY Patient Care Program objectives are met.

I may cancel this healthcare facility registration in the future by notifying Lilly in writing and submitting the notification by fax to 1-877-772-9391 or by calling 1-877-772-9390. If I revoke this facility's registration, the facility will no longer be eligible to administer ZYPREXA RELPREVY to patients.

______________________________________________  Date:  ________________
Authorized Healthcare Facility Representative Signature  month  day  year

______________________________________________  Title  ______________________
Authorized Healthcare Facility Representative Name (print)

Please fax completed form to the ZYPREXA RELPREVY Patient Care Program at 1-877-772-9391.

PHONE 1-877-772-9390  FAX 1-877-772-9391  www.zyprexaelprevyprogram.com

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Reference ID: 4417451
MULTIPLE PATIENT INJECTION FORM

IMPORTANT: Before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection. Submit this information within 7 days after the patient's injection. If you are aware that the patient's prescriber has changed, please notify the ZYPREXA RELPREVY Patient Care Program Coordinating Center.

Injection Facility Name: ____________________________

Date of Injection

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Patient No.: (PIN)

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Patient Info.

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Date of Birth:

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PDSS since last visit? (check one)

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<th>Yes</th>
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If Yes, has the prescriber been notified of the PDSS event?

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<th>Yes</th>
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Time of Injection (24-hour clock)

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Dose of Injection (check one)

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<th>150 mg</th>
<th>210 mg</th>
<th>300 mg</th>
<th>405 mg</th>
<th>Other dose</th>
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Observed at least 3 hours post-injection? (check one)

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<th>Yes</th>
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PDSS during onsite observation? (check one)

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<th>Yes</th>
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If Yes, has the prescriber been notified of the PDSS event?

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<th>Yes</th>
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Following the injection, was the patient alert, oriented, and absent of any signs and symptoms of PDSS prior to being released from the healthcare facility? (check one)

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<th>Yes</th>
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Following the injection, was the patient accompanied from the facility? (check one)

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<th>Yes</th>
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Not applicable, patient did not leave facility (in-patient)

Signature

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<th>Healthcare Facility Staff Member Signature</th>
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<th>Healthcare Facility Staff Member Name (print)</th>
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<tr>
<th>Healthcare Facility Staff Member Name (print)</th>
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Was the patient or legal guardian given a Medication Guide prior to this injection?

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<th>Yes</th>
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PHONE 1-877-729-90 FAX 1-877-772-9391 www.zelrrg.m

Version 2.0 03Aug2012 CONFIDENTIAL age

Reference ID: 4417451
PATIENT INFORMATION

First Name: ___________________________ MI: _____ Last Name: ___________________________

Date: ________________________________

PATIENT AGREEMENT

The maker of ZYPREXA RELPREVV, Eli Lilly and Company and their delegates run the ZYPREXA RELPREVV Patient Care Program.

Your doctor will send you your name, date of birth, and other information that directly identifies you to the ZYPREXA RELPREVV Patient Care Program. Ask your doctor if you have questions about the information that will be collected.

The ZYPREXA RELPREVV Patient Care Program will collect and use your information in the following ways:

• Your doctor will provide dose, date and time of each injection, and other medical information to the ZYPREXA RELPREVV Patient Care Program.

• Your information will be stored in the ZYPREXA RELPREVV Patient Care Program computer system.

• The information will be used to help Lilly learn more about the safety of ZYPREXA RELPREVV.

• Information from all patients in the ZYPREXA RELPREVV Patient Care Program will be reviewed and may be combined with information from clinical studies.

• This combined information will not be able to identify you or any other patient. This combined information may be shared with:
  • regulatory agencies,
  • doctors at other institutions,
  • the committee overseeing the ZYPREXA RELPREVV Patient Care Program, and/or
  • publications or as part of scientific discussions.

Also, by signing this form you agree to the following:

• I understand that I must enroll in the ZYPREXA RELPREVV Patient Care Program registry to get ZYPREXA RELPREVV.

• I agree to have my information entered in the ZYPREXA RELPREVV Patient Care Program registry.

• My doctor has explained the risks and benefits of treatment with ZYPREXA RELPREVV.

• I have received a copy of the Medication Guide.

• I understand that I will be observed at the clinic for 3 hours after each injection.

• Someone must go with me to my destination when I leave the clinic.

• I understand that I can not drive or use heavy machinery for the rest of the day on which I get an injection.

• I agree to seek medical care right away if I have a reaction such as excessive sleepiness, dizziness, confusion, difficulty talking, difficulty walking, muscle stiffness or shaking, weakness, irritability, aggression, anxiety, increase in blood pressure or convulsions.

• I agree to contact my doctor if I have a reaction to ZYPREXA RELPREVV.

• I may be asked to complete occasional surveys about my understanding of the risks and benefits of treatment with ZYPREXA RELPREVV.

• I or my caregiver have discussed any questions or concerns about my treatment with ZYPREXA RELPREVV with my doctor.

You may stop participating in the ZYPREXA RELPREVV Patient Care Program at any time by telling your doctor. If you stop participating, you will no longer be able to receive the drug. Your doctor will no longer provide any of your information to the ZYPREXA RELPREVV Patient Care Program except to answer safety questions. The ZYPREXA RELPREVV Patient Care Program will still use information that was collected before you stopped participating. You will be provided a copy of this form.
To be enrolled in the ZYPREXA RELPREVV Patient Care Program, complete and fax this form to 1-877-772-9391.

**PATIENT INFORMATION**

First Name: ___________________________ MI: _____ Last Name: ___________________________

Date of Birth: ___________________________

Gender:  □ Male  □ Female

Race:  □ White  □ Black or African American  □ Native Hawaiian or Other Pacific Islander
 □ Asian  □ American Indian or Alaska Native  □ Other

Ethnicity:  □ Hispanic or Latino
 □ Non-Hispanic/Non-Latino

**PRESCRIBER INFORMATION**

First Name: ___________________________ MI: _____ Last Name: ___________________________

License Number: ___________________________ State of Issue: ___________________________

Treatment Facility/Practice Name (where you see the patient): ___________________________

Address Line 1: ___________________________

Address Line 2: ___________________________

Will the patient be injected/monitored at your facility/practice?

□ Yes
□ No  (If No, complete next section)

**INJECTING/MONITORING FACILITY INFORMATION**

Facility Name (where the patient receives injections or monitoring): ___________________________

Address Line 1: ___________________________

Address Line 2: ___________________________

City: ___________________________ State: ___________ Zip: ___________________________
PATIENT AGREEMENT

The maker of ZYPREXA RELPREVX, Eli Lilly and Company and their delegates run the ZYPREXA RELPREVX Patient Care Program.

Your doctor will send your name, date of birth, and other information that directly identifies you to the ZYPREXA RELPREVX Patient Care Program. Ask your doctor if you have questions about the information that will be collected.

The ZYPREXA RELPREVX Patient Care Program will collect and use your information in the following ways:

- Your doctor will provide dose, date and time of each injection, and other medical information to the ZYPREXA RELPREVX Patient Care Program.
- Your information will be stored in the ZYPREXA RELPREVX Patient Care Program computer system.
- The information will be used to help Lilly learn more about the safety of ZYPREXA RELPREVX.
- Information from all patients in the ZYPREXA RELPREVX Patient Care Program will be reviewed and may be combined with information from clinical studies.
- This combined information will not be able to identify you or any other patient. This combined information may be shared with:
  - regulatory agencies,
  - doctors at other institutions,
  - the committee overseeing the ZYPREXA RELPREVX Patient Care Program, and/or
  - publications or as part of scientific discussions.

Also, by signing this form you agree to the following:

- I understand that I must enroll in the ZYPREXA RELPREVX Patient Care Program registry to get ZYPREXA RELPREVX.
- I agree to have my information entered in the ZYPREXA RELPREVX Patient Care Program registry.
- My doctor has explained the risks and benefits of treatment with ZYPREXA RELPREVX.
- I have received a copy of the Medication Guide.
- I understand that I will be observed at the clinic for 3 hours after each injection.
- Someone must go with me to my destination when I leave the clinic.
- I understand that I can not drive or use heavy machinery for the rest of the day on which I get an injection.
- I agree to seek medical care right away if I have a reaction such as excessive sleepiness, dizziness, confusion, difficulty talking, difficulty walking, muscle stiffness or shaking, weakness, irritability, aggression, anxiety, increase in blood pressure or convulsions.
- I agree to contact my doctor if I have a reaction to ZYPREXA RELPREVX.
- I may be asked to complete occasional surveys about my understanding of the risks and benefits of treatment with ZYPREXA RELPREVX.
- I or my caregiver have discussed any questions or concerns about my treatment with ZYPREXA RELPREVX with my doctor.

You may stop participating in the ZYPREXA RELPREVX Patient Care Program at any time by telling your doctor. If you stop participating, you will no longer be able to receive the drug. Your doctor will no longer provide any of your information to the ZYPREXA RELPREVX Patient Care Program except to answer safety questions. The ZYPREXA RELPREVX Patient Care Program will still use information that was collected before you stopped participating. You will be provided a copy of this form.

________________________
Signature

Date: ____________
month - ____________ day - ____________ year

Printed Name of Patient

Printed Name of Legal Guardian (if applicable)

☐ Check the box if the patient has not signed due to enrollment decision being made by prescriber who is authorized via a court order.

Date of Court Order Expiration (MMDDYYYY) __________________________

☐ This patient has been shown to be tolerant of oral olanzapine.

________________________
Signature of Prescriber

Date: ____________
month - ____________ day - ____________ year

Printed Name of Prescriber
POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Submit this information within 24 hours of becoming aware of a suspected PDSS event.

Patient No
(PIN)

Patient Name:
First Name
MI
Last Name

Date of Birth:
month
day
year

Does the patient have a diagnosis of schizophrenia?  □ Yes  □ No

PATIENT/INJECTION INFORMATION

Date of Injection:
month
day
year

Time of ZYPREXA RELPREVV Injection: [ ] : [ ]

CONVENIENCE KIT PACKAGE

Lot #

ONSET OF FIRST PDSS SYMPTOM AFTER INJECTION (choose only one)

□ 1 - 15 minutes  □ 46 - 60 minutes  □ 121 - 150 minutes (2 ½ hours)
□ 16 - 30 minutes  □ 61 - 90 minutes (1 ½ hours)  □ 151 - 180 minutes (3 hours)
□ 31 - 45 minutes  □ 91 - 120 minutes (2 hours)  □ If greater than 3 hours please specify:

□ Dose of Injection:  □ 150 mg  □ 210 mg  □ 300 mg  □ 405 mg  □ Other dose ______ mg

□ Was the injection given in gluteal muscle?  □ Yes  □ No

Height: [ ] inches  □ Weight: [ ] lbs.

PDSS SIGNS AND SYMPTOMS

Please mark the signs and symptoms that the patient experienced (check all that apply).

□ Aggressiveness  □ Coma  □ Hypertension  □ Tachycardia
□ Agitation  □ Confusion  □ Hypotension  □ Various extrapyramidal symptoms
□ Anxiety  □ Convulsion/Seizure  □ Other cognitive impairment  □ Weakness
□ Aspiration  □ Delirium  □ Possible neuroleptic malignant syndrome  □ Other ______
□ Ataxia  □ Disorientation  □ Reduced level of consciousness  □ Other ______
□ Cardiac arrhythmias  □ Dizziness  □ Respiratory depression  □ Other ______
□ Cardiopulmonary arrest  □ Dysarthria  □ Sedation  □ Other ______
POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.: ________________
(PIN)

Patient Name: _____________________________
First Name ________________________ MI _____ Last Name _____________________________

PDSS start date: __________-______-________
Month Day Year

PDSS resolution date: __________-______-________
Month Day Year
OR ☐ Ongoing

If resolved, duration of PDSS: _____________________________ ☐ Minutes ☐ Hours ☐ Days

Are these PDSS symptoms related to ZYPREXA RELPREVV?
☐ Yes
☐ No - Please Explain _____________________________

Describe the clinical course _____________________________

Patient Outcome: (choose one) ☐ Recovered ☐ Fatal ☐ Not Recovered
☐ Unknown ☐ Recovering ☐ Recovered with sequelae

Once a PDSS event was suspected, was the patient’s monitoring initiated in a facility capable of resuscitation?
☐ Yes ☐ No

Did the patient visit the emergency room as a result of the PDSS?
☐ Yes ☐ No

Was the patient admitted to the hospital as a result of the PDSS?
☐ Yes ☐ No

Were olanzapine concentrations collected?
☐ Yes ☐ No

Did the patient receive any MEDICATIONS AS TREATMENT for the PDSS event?
☐ Yes - Please record below ☐ No

<table>
<thead>
<tr>
<th>Treatment Medication Name</th>
<th>Dose</th>
<th>Duration of Use (in Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Phone 1-877-772-9390
FAX 1-877-772-9391
www.zyprexarelprevvprogram.com
POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.: □ □ □ □ □ □
(PIN)
Patient Name: ____________________________________________
      First Name                 MI              Last Name

Did the patient receive any NON-PHARMACEUTICAL TREATMENTS or
DIAGNOSTIC TESTS associated with this event?  □ Yes - Please record below □ No

☐ Assisted ventilation    ☐ EEG    ☐ MRI
☐ Brain CT                ☐ IV fluids ☐ Observation/symptomatic management
☐ ECG                     ☐ Labs     ☐ Restraints
☐ Other ____________________

Please fax test results to 1-877-772-9391.

HISTORY PRIOR TO PDSS EVENT

Does the patient have any relevant comorbidities?
□ Yes - Please specify: ____________________________________________
□ No

PRIOR MEDICATIONS

Did the patient take any medications during the 24 hours prior to the injection?  □ Yes - Please record below □ No

<table>
<thead>
<tr>
<th>Prior Medication Name</th>
<th>Dose</th>
<th>Duration of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Number</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Days</td>
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<td>Days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Days</td>
</tr>
</tbody>
</table>

Did the patient use any of the following during the 24 hours prior to the injection?  □ Yes - Please record below □ No

☐ Alcohol
☐ Amphetamines/Methamphetamines
☐ Barbiturates
☐ Cannabinoid
☐ Cocaine
☐ Hallucinogens
☐ Opiates
☐ Phencyclidine

Event reported by: ____________________________________________

First       MI       Last

Title/Occupation: ____________________________________________

If agent of the Prescriber, name of Prescriber: ____________________________________________

Phone 1-877-772-9390       FAX 1-877-772-9391       www.zyprexarelprevprogram.com

Version 1.0 28Oct2009
CONFIDENTIAL
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Lilly

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Reference ID: 4417451
PHARMACY REGISTRATION FORM

To be enrolled in the ZYPREXA RELPREVV Patient Care Program, complete and fax this form to 1-877-772-9391.

Training must be completed before a pharmacy may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

### PHARMACY INFORMATION

- **Enrollment**
- **Reenrollment**

**Pharmacy/Hospital Name:**

- **Pharmacy DEA Number:**

**Please specify description of Pharmacy:**

- Community/Retail
- Specialty Pharmacy
- Hospital or Institution
- Other

**Address Line 1:**

**Address Line 2:**

**City:** ____________  **State:** ____________  **Zip:** ____________

**Primary Phone:** ____________  **Secondary Phone:** ____________

**Fax:** ____________

### SHIP TO INFORMATION

Ship To Address (if the same as above, check here): □

**Ship To Contact Name:**

**Address Line 1:**

**Address Line 2:**

**City:** ____________  **State:** ____________  **Zip:** ____________

**Primary Phone:** ____________  **Secondary Phone:** ____________

**Fax:** ____________

### PHARMACIST-IN-CHARGE INFORMATION

**First Name:** ____________  **MI:** ____________  **Last Name:** ____________

**Email:** ____________

**Phone:** ____________  **Fax:** ____________

(if different from above)

(if different from above)

**PHARMACIST-IN-CHARGE INFORMATION**

By signing below, I acknowledge that:

- I have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.
- I will ensure that all appropriate pharmacy staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.
- I will ensure that all appropriate pharmacy staff understand that ZYPREXA RELPREVV can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.
- I will ensure that pharmacy staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to dispensing each prescription/refill by accessing the system.
- I will ensure that pharmacy staff will not dispense ZYPREXA RELPREVV directly to patients.
- I will ensure pharmacy staff report the date of each ZYPREXA RELPREVV dispensing to the ZYPREXA RELPREVV Patient Care Program.
- For each dispense I will ensure prescription verification (includes patient eligibility check and recording the dispense date) is completed on the date of dispense, prior to the visit or leaving the pharmacy.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the pharmacy to clarify information provided or obtain information about the patient.

I may cancel this registration by notifying the ZYPREXA RELPREVV Patient Care Program Coordinating Center by fax at 1-877-772-9390 or by phone at 1-877-772-9390. If I cancel, Lilly will cease to supply ZYPREXA RELPREVV to the pharmacy.

**Pharmacist-in-Charge Signature**

**Date:**

- **month:** ____________
- **day:** ____________
- **year:** ____________

PHONE 1-877-772-9390  FAX 1-877-772-9391  www.zyprexaelprevvprogram.com

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To be enrolled in the ZYPREXA RELPREVY Patient Care Program, complete and fax this form to 1-877-772-9391.

Training must be completed before a prescriber may be enrolled in the ZYPREXA RELPREVY Patient Care Program.

**PRESCRIBER INFORMATION**

- [ ] Enrollment
- [ ] Reenrollment

First Name: ___________________________ MI: ________ Last Name: ___________________________

Degree: [ ] MD [ ] DO [ ] NP [ ] PA [ ] Nurse with prescriptive authority [ ] Other with prescriptive authority

License Number: ___________________________ State of Issue: ___________________________

Treatment Facility/Practice (Where you see your patients):

If you see your patients at multiple locations please contact the ZYPREXA RELPREVY Patient Care Program Coordinating Center to provide additional facility/practice information

Address Line 1: ___________________________

Address Line 2: ___________________________

City: ___________________________ State: __________ Zip: ___________________________

Phone: ___________________________ Alternate Phone: ___________________________

Fax: ___________________________ Prescriber Email: ___________________________

Preferred Method of Communication: [ ] Email [ ] Fax

**PRESCRIBER AGREEMENT**

By signing below, I acknowledge that:

- I understand the ZYPREXA RELPREVY Patient Care Program requirements and the risks associated with ZYPREXA RELPREVY.
- I have completed the mandatory ZYPREXA RELPREVY training.
- I understand the clinical presentation of post-injection delirium/sedation syndrome (PDSS) and how to manage patients should an event occur while using ZYPREXA RELPREVY.
- I understand that ZYPREXA RELPREVY should only be initiated in patients for whom tolerability with oral olanzapine has been established.
- I understand that ZYPREXA RELPREVY should only be administered to patients in healthcare settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.
- I will enroll all patients in the ZYPREXA RELPREVY Patient Care Program registry prior to prescribing ZYPREXA RELPREVY by completing the Patient Registration Form.
- I will ensure all suspected cases of PDSS are reported to the ZYPREXA RELPREVY Patient Care Program within 24 hours of becoming aware of the event.
- I will review the ZYPREXA RELPREVY Medication Guide with each patient prior to prescribing.
- I understand that the ZYPREXA RELPREVY Patient Care Program Coordinating Center may contact me to resolve discrepancies, to obtain information about a patient, or to conduct occasional surveys.

I may cancel this registration by notifying the ZYPREXA RELPREVY Patient Care Program Coordinating Center by fax at 1-877-772-9391 or by phone at 1-877-772-9390.

If I revoke my registration, I will no longer be eligible to prescribe ZYPREXA RELPREVY.

Lilly may disenroll prescribers that are non-compliant with the program requirements.

Prescriber Signature ___________________________ Date: ___________________________

month - day - year
### SINGLE PATIENT INJECTION FORM

**IMPORTANT:** Before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection.

Submit this information within 7 days after the patient's injections. If you are aware that the patient's prescriber has changed, please notify the ZYPREXA RELPREVV Patient Care Program Coordinating Center.

<table>
<thead>
<tr>
<th>Patient No.: (PIN)</th>
<th>Injection Facility Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Birth:</th>
</tr>
</thead>
<tbody>
<tr>
<td>month</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

PDSS since the last visit? (After the patient left the office, following his/her previous injection, did the patient experience post-injection delirium/sedation syndrome?)

- [ ] No
- [ ] Yes

If Yes, has the prescriber been notified of the PDSS event?

- [ ] Yes
- [ ] No

### ZYPREXA RELPREVV TREATMENT

<table>
<thead>
<tr>
<th>Date of Injection:</th>
</tr>
</thead>
<tbody>
<tr>
<td>month</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time of ZYPREXA RELPREVV injection:</th>
</tr>
</thead>
<tbody>
<tr>
<td>24-hour clock</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dose of Injection:</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 mg</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Was the patient observed for at least 3 hours post-injection?  
- [ ] Yes
- [ ] No

Did the patient experience post-injection delirium/sedation syndrome during the onsite post-injection observational period?

- [ ] No
- [ ] Yes

If Yes, has the prescriber been notified of the PDSS event?  
- [ ] Yes
- [ ] No

Following the injection, was the patient alert, oriented, and absent of any signs and symptoms of PDSS prior to being released from the healthcare facility?  
- [ ] Yes
- [ ] No

Following the injection, was the patient accompanied from the facility?  

- [ ] Yes
- [ ] No
- [ ] Not applicable, patient did not leave facility (in-patient)

Was the patient or legal guardian given a Medication Guide prior to this injection?  

- [ ] Yes
- [ ] No

Healthcare Facility Staff Member Signature:  

______

Healthcare Facility Staff Member Name (print):  

______

**PHONE 1-877-772-9390**  
**FAX 1-877-772-9391**  
**www.zyprexarelpervvprogram.com**

Reference ID: 4417451
HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ZYPREXA RELPREVIV safely and effectively. See full prescribing information for ZYPREXA RELPREV.
ZYPREXA RELPREV (olanzapine) For Extended Release Injectible Suspension
Initial U.S. Approval: 1996

WARNING: POST-INJECTION DELIRIUM/SEDATION SYNDROME AND INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

See full prescribing information for complete boxed warning.

- Patients are at risk for severe sedation (including coma) and/or delirium after each injection and must be observed for at least 3 hours in a registered facility with ready access to emergency response services. Because of this risk, ZYPREXA RELPREV is available only through a restricted distribution program called ZYPREXA RELPREV Patient Care Program and requires prescriber, healthcare facility, patient, and pharmacy enrollment. (2.1, 5.1, 5.2, 10.2, 17.2)

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ZYPREXA RELPREV is not approved for the treatment of patients with dementia-related psychosis. (5.3, 5.16, 17.2)

RECENT MAJOR CHANGES

NEW

- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Discontinue if DRESS is suspected. (5.9)
- Metabolic Changes: Abnormal antipsychotic drugs have been associated with metabolic changes including hyperglycemia, diabetes mellitus. In some cases severe and associated with ketonuria or hyperosmolar coma or death, has been reported in patients taking olanzapine. Patients taking olanzapine should be monitored for symptoms of hyperglycemia and undergo fasting blood glucose testing at the beginning of, and periodically during, treatment. (5.7)
- Dyslipidemia: Unusual elevations in lipids have been observed. Appropriate clinical monitoring is recommended, including testing blood lipid testing at the beginning of, and periodically during, treatment. (5.7)
- Weight Gain: Potential consequences of weight gain should be considered. Patients should receive regular monitoring of weight. (5.7)
- Tartrate Dyskinesia/Disorder if clinically appropriate. (5.9)
- Orthostatic Hypotension: Orthostatic hypotension associated with dizziness, lightheadedness, and in some patients, syncope, may occur especially during initial dose titration. Use caution in patients with cardiovascular disease, cerebrovascular disease, and those conditions that could affect hemodynamic responses. (5.9)
- Leukopenia, Neutropenia, and Agranulocytosis have been reported with antipsychotics, including ZYPREXA. Patients with a history of a clinically significant white blood cell count (WBC) or drug-induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and discontinuation of ZYPREXA RELPREV should be considered at the first sign of a clinically significant decrease in WBC in the absence of other causative factors. (5.11)
- Seizures: Use cautiously in patients with a history of seizures or conditions that potentially lower the seizure threshold. (5.13)
- Potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Use caution when operating machinery. (5.14)
- Hyperprolactinemia: May elevate prolactin levels. (5.17)
- Laboratory Tests: Monitor fasting blood glucose and lipid profiles at the beginning of, and periodically during, treatment. (5.16)

ADVERSE REACTIONS

Most common adverse reactions (≥ 5% in at least one of the treatment groups and greater than placebo) associated with ZYPREXA RELPREV: treatment: headache, sedation, weight gain, cough, diarrhea, back pain, nausea, somnolence, dry mouth, nasopharyngitis, increased appetite, and vomiting. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Eli Lilly and Company at 1-800-Lilly Rx (1-800-545-7709) or FDA at 1-888-FLY-SPID or www.fda.gov/medwatch

DRUG INTERACTIONS

- CNS-Acting Drugs: Caution should be used when used in combination with other centrally acting drugs and alcohol. (7.2)
- Antipsychotic Agents: Enhanced antipsychotic effect. (7.2)
- Loxapine and Oxpipramine Agonists May antagonize loxapine/dopamine agonists. (7.2)
- Diazepam: May potentiate orthostatic hypotension. (7.1, 7.2)
- Alcohol: May potentiate orthostatic hypotension. (7.1)
- Carbamazepine: Increased clearance of olanzapine. (7.1)
- Fluoxetine: May increase fluoxetine levels. (7.1)

USE IN SPECIFIC POPULATIONS

- Pregnancy: ZYPREXA RELPREV should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (8.1)
- Nursing Mothers: Breast-feeding is not recommended. (8.3)
- Pediatric Use: Safety and effectiveness of ZYPREXA RELPREV in children ≤18 years of age have not been established. (8.4)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved Medication Guide

Revised: 06/2018

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: POST-INJECTION DELIRIUM/SEDATION SYNDROME AND INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

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1.1 Schizophrenia

2 DOSAGE AND ADMINISTRATION
2.1 Intramuscular

2.2 Instructions to Reconstitute and Administer ZYPREXA RELPREV

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS
5.1 Post-Injection Delirium/Sedation Syndrome
5.2 Prescribing and Distribution Program for ZYPREXA RELPREV
5.3 Elderly Patients with Dementia-Related Psychosis
5.4 Suicide
5.5 Neuroleptic Malignant Syndrome (NMS)
5.6 Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
5.7 Metabolic Changes
5.8 Tardive Dyskinesia
5.9 Orthostatic Hypotension
5.10 Falls
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5.12 Dyspnea
5.13 Gastrointestinal
5.14 Potential for Cognitive and Motor Impairment
5.15 Body Temperature Regulation
5.16 Use in Patients with Congestive Heart Failure

ZYPREXA RELPREV (olanzapine) For Extended Release Injectable Suspension ZYPREXA RELPREV (olanzapine) For Extended Release Injectable Suspension

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5.18 Laboratory Tests

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7.1 Potential for Other Drugs to Affect Olanzapine
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8 USE IN SPECIFIC POPULATIONS
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9.3 Dependence

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10.2 Management of Overdose

11 DESCRIPTION

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16.2 Storage and Handling

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17.10 Potential for Cognitive and Motor Impairment
17.11 Body Temperature Regulation
17.12 Concomitant Medication
17.13 Alcohol
17.14 Use in Specific Populations

*Sections or subsections omitted from the full prescribing information are not listed

ZYPREXA RELPREV (olanzapine) For Extended Release Injectable Suspension ZYPREXA RELPREV (olanzapine) For Extended Release Injectable Suspension ZYPREXA RELPREV (olanzapine) For Extended Release Injectable Suspension
1 INDICATIONS AND USAGE

ZYPREXA RELPREVV is indicated for the treatment of schizophrenia. Efficacy was established in two clinical trials in patients with schizophrenia: one 8-week trial in adults and one maintenance trial in adults [see Clinical Studies (14.1)].

2 DOSAGE AND ADMINISTRATION

2.1 Dose

ZYPREXA RELPREVV is intended for deep intramuscular gluteal injection only and should not be administered intravenously or subcutaneously.

Step Selection — The efficacy of ZYPREXA RELPREVV has been demonstrated within the range of 150 mg to 300 mg administered every 2 weeks and with 405 mg administered every 4 weeks. Dose recommendations considering oral ZYPREXA and ZYPREXA RELPREVV are shown in Table 1.

Table 1: Recommended Dosing for ZYPREXA RELPREVV

<table>
<thead>
<tr>
<th>Target Oral ZYPREXA Dose</th>
<th>Dosing of ZYPREXA RELPREVV During the First 8 Weeks</th>
<th>Maintenance Dose of ZYPREXA RELPREVV Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg/day</td>
<td>210 mg/2 weeks or 405 mg/4 weeks</td>
<td>150 mg/2 weeks or 300 mg/4 weeks</td>
</tr>
<tr>
<td>15 mg/day</td>
<td>300 mg/2 weeks or 405 mg/4 weeks</td>
<td>210 mg/2 weeks or 300 mg/4 weeks</td>
</tr>
<tr>
<td>20 mg/day</td>
<td>300 mg/2 weeks</td>
<td>300 mg/2 weeks</td>
</tr>
</tbody>
</table>

ZYPREXA RELPREVV doses greater than 405 mg every 4 weeks or 300 mg every 2 weeks have not been evaluated in clinical trials.

1.1 Schizophrenia

ZYPREXA RELPREVV is indicated for the treatment of schizophrenia. Efficacy was established in two clinical trials in patients with schizophrenia: one 8-week trial in adults and one maintenance trial in adults [see Clinical Studies (14.1)].

1.2 Dosage

ZYPREXA RELPREVV is intended for deep intramuscular gluteal injection only and should not be administered intravenously or subcutaneously.

Be aware that there are two ZYPREXA intramuscular formulations with different dosing schedules. ZYPREXA Intramuscular (10 mg/vial) is a short-acting formulation and should not be confused with ZYPREXA RELPREVV. Refer to the package insert for ZYPREXA Intramuscular for more information about that product.

Establish tolerability with oral olanzapine prior to initiating treatment.

ZYPREXA RELPREVV should be administered by a healthcare professional every 2 to 4 weeks by deep intramuscular gluteal injection using a 19-gauge, 1.5-inch needle. Following insertion of the needle into the muscle, aspiration should be maintained for several seconds to ensure that no blood is drawn into the syringe. If any blood is aspirated into the syringe, it should be discarded and fresh drug should be prepared using a new convenience kit. The injection should be performed at a steady, continuous pressure. Do not massage the injection site.

Dose Selection — The efficacy of ZYPREXA RELPREVV has been demonstrated within the range of 150 mg to 300 mg administered every 2 weeks and with 405 mg administered every 4 weeks. Dose recommendations considering oral ZYPREXA and ZYPREXA RELPREVV are shown in Table 1.

Table 1: Recommended Dosing for ZYPREXA RELPREVV

<table>
<thead>
<tr>
<th>Target Oral ZYPREXA Dose</th>
<th>Dosing of ZYPREXA RELPREVV During the First 8 Weeks</th>
<th>Maintenance Dose of ZYPREXA RELPREVV Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg/day</td>
<td>210 mg/2 weeks or 405 mg/4 weeks</td>
<td>150 mg/2 weeks or 300 mg/4 weeks</td>
</tr>
<tr>
<td>15 mg/day</td>
<td>300 mg/2 weeks or 405 mg/4 weeks</td>
<td>210 mg/2 weeks or 300 mg/4 weeks</td>
</tr>
<tr>
<td>20 mg/day</td>
<td>300 mg/2 weeks</td>
<td>300 mg/2 weeks</td>
</tr>
</tbody>
</table>

2.2 Instructions to Reconstitute and Administer ZYPREXA RELPREVV

For deep intramuscular gluteal injection only. Not to be injected intravenously or subcutaneously. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Step 1: Preparing Materials

Convenience kit includes:

- Vial of ZYPREXA RELPREVV powder
- 3-mL vial of diluent
- One 3-mL syringe with pre-attached 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro® needle with needle protection device
- Two 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needles with needle protection device

For obese patients, a 2-inch (50 mm), 19-gauge or larger needle (not included in convenience kit) may be used for administration.

ZYPREXA RELPREVV must be suspended using only the diluent supplied in the convenience kit.

It is recommended that gloves are used when reconstituting, as ZYPREXA RELPREVV may be irritating to the skin. Flush with water if contact is made with skin.

See additional insert entitled “Instructions to Reconstitute and Administer ZYPREXA RELPREVV” (included) for more information regarding the safe and effective use of the Hypodermic Needle-Pro syringe and needle.

Step 2: Determining Reconstitution Volume

Refer to the table below to determine the amount of diluent to be added to powder for reconstitution of each vial strength.

It is important to note that there is more diluent in the vial than is needed to reconstitute.

<table>
<thead>
<tr>
<th>Dose</th>
<th>Vial Strength</th>
<th>Diluent to Add</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 mg</td>
<td>210 mg</td>
<td>1.3 mL</td>
</tr>
<tr>
<td>210 mg</td>
<td>210 mg</td>
<td>1.3 mL</td>
</tr>
<tr>
<td>300 mg</td>
<td>300 mg</td>
<td>1.8 mL</td>
</tr>
<tr>
<td>405 mg</td>
<td>405 mg</td>
<td>2.3 mL</td>
</tr>
</tbody>
</table>

Step 3: Reconstituting ZYPREXA RELPREVV

Please read the Hypodermic Needle-Pro Instructions for Use before proceeding with Step 3. Failure to follow these instructions may result in a needlestick injury. Loosen the powder by lightly tapping the vial.

ZYPREXA RELPREVV (olanzapine) For Extended Release Injectable Suspension ZYPR-0007-USPI-20180119
Open the prepackaged Hypodermic Needle-Pro syringe and needle with needle protection device.
Withdraw the pre-determined diluent volume (Step 2) into the syringe.
Inject the diluent into the powder vial.
Withdraw air to equalize the pressure in the vial by pulling back slightly on the plunger in the syringe.
Remove the needle from the vial, holding the vial upright to prevent any loss of material.
Engage the needle safety device (refer to complete Hypodermic Needle-Pro Instructions for Use).
Ped a hard surface to cushion impact (see Figure 1). Tap the vial firmly and repeatedly on the surface until no powder is visible.

Figure 1: Tap firmly to mix.

Visually check the vial for clumps. Unsuspended powder appears as yellow, dry clumps clinging to the vial. Additional tapping may be required if large clumps remain (see Figure 2).

Figure 2: Check for unsuspended powder and repeat tapping if needed.

Shake the vial vigorously until the suspension appears smooth and is consistent in color and texture. The suspended product will be yellow and opaque (see Figure 3).

Figure 3: Vigorously shake vial.

If foam forms, let vial stand to allow foam to dissipate.
If the product is not used right away, it should be shaken vigorously to re-suspend. Reconstituted ZYPREXA RELPRES remains stable for up to 24 hours in the vial.

Step 4: Injecting ZYPREXA RELPRES

Before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection.
Refer to the table below to determine the final volume to inject. Suspension concentration is 150 mg/mL ZYPREXA RELPRES.

<table>
<thead>
<tr>
<th>Dose (mg)</th>
<th>Final Volume to Inject</th>
</tr>
</thead>
<tbody>
<tr>
<td>150</td>
<td>1 mL</td>
</tr>
<tr>
<td>210</td>
<td>1.4 mL</td>
</tr>
<tr>
<td>300</td>
<td>2 mL</td>
</tr>
<tr>
<td>405</td>
<td>2.7 mL</td>
</tr>
</tbody>
</table>

ZYPREXA RELPRES (olanzapine)
For Extended Release Injectable Suspension

ZYPREXA RELPRES (olanzapine)
For Extended Release Injectable Suspension

Attach a new safety needle to the syringe.
Slowly withdraw the desired amount into the syringe.
Some excess product will remain in the vial.

For administration, select the 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needle with needle protection device. For obese patients, a 21-gauge (50 L) 19-gauge or larger needle (not included in convenience kit) may be used. To help prevent clogging, a 19-gauge or larger needle must be used.

Attach the new safety needle to the syringe prior to injection. Once the suspension has been removed from the vial, it should be injected immediately.

For deep intramuscular glutethimide injection only. Do not inject intravenously or subcutaneously.
Select and prepare a site for injection in the gluteal area.
After insertion of the needle into the muscle, aspirate for several seconds to ensure that no blood appears. If any blood is drawn into the syringe, discard the syringe and the dose and begin with a new convenience kit. The injection should be performed with steady, continuous pressure.

Do not massage the injection site.
Engage the needle safety device.
Dispose of the vials, needles, and syringe appropriately after injection. The vial is for single-use only.

3 DOSE FORMS AND STRENGTHS
ZYPREXA RELPRES is a powder for suspension for intramuscular use only. ZYPREXA RELPRES is present as a yellow solid in a glass vial equivalent to 210, 300, or 405 mg olanzapine per vial. The diluent is a clear, colorless to slightly yellow solution in a glass vial [see Description (11) and How Supplied/Storage and Handling (16)]. The reconstituted suspension will be yellow and opaque [see Dosage and Administration (2.2)].

4 CONTRAINDICATIONS
None.

5 WARNINGS AND PRECAUTIONS
5.1 Post-Injection Delirium/Sedation Syndrome

During premarketing clinical studies of ZYPREXA RELPRES, adverse events that presented with signs and symptoms consistent with delirium or oversedation, in particular oversedation (including coma) or delirium, were reported in patients following an injection of ZYPREXA RELPRES [see Boxed Warning and Dose and Administration (2.1)]. These events occurred in 4.9% of patients and in approximately 2% of patients who received injections for up to 46 months. These events were correlated with an unintentional rapid increase in serum olanzapine concentrations to supra-therapeutic ranges in some cases. While a rapid and greater than expected increase in serum olanzapine concentration has been observed in some patients with these events, the exact mechanism by which the drug was unintentionally introduced into the blood stream is not known. Clinical signs and symptoms included dizziness, confusion, disorientation, slurred speech, altered gait, difficulty ambulating, weakness, agitation, extrapyramidal symptoms, hypotension, conduction, and reduced level of consciousness ranging from mild sedation to coma. Time after injection to event ranged from soon after injection to greater than 4 hours after injection. The majority of patients were hospitalized and some required supportive care, including intubation, in several cases. At least 3 hours had largely recovered by 72 hours. The risk of an event is the same at each injection, so the risk per patient is cumulative (i.e., increases with the number of injections) [see Overdosage (10.1)]. Healthcare professionals are advised to discuss this potential risk with patients each time they prescribe and administer ZYPREXA RELPRES [see Patient Counseling Information (17.1, 17.2)].

5.2 Prescribing and Distribution Program for ZYPREXA RELPRES
ZYPREXA RELPRES is available only through a restricted distribution program [see Boxed Warning, Indications and Usage (1), and Patient Counseling Information (17.2)]. ZYPREXA RELPRES must not be dispensed directly to a patient. For a patient to receive treatment, the prescriber, healthcare facility, patient, and pharmacy must all be enrolled in the ZYPREXA RELPRES Patient Care Program. To enroll, call 1-877-772-9390.
ZYPREXA RELPRES must be administered in a registered healthcare facility (such as a hospital, clinic, residential treatment center, or community healthcare center) with ready access to emergency response services. After each ZYPREXA RELPRES injection, a healthcare professional must continuously observe the patient at the healthcare facility for at least 4 hours and must confirm that the patient is alert, oriented, and absent of any signs and symptoms of post-injection delirium/sedation syndrome prior to being released. All patients must be accompanied to their destination upon leaving the facility. For the remainder of the day of each injection, patients should not drive or operate heavy machinery, and should be advised to be vigilant for symptoms of post-injection delirium/sedation syndrome and be able to obtain medical assistance if needed. If post-injection delirium/sedation syndrome is suspected, close medical supervision and monitoring should be instituted in a facility capable of resuscitation [see Overdosage (10)]. If parental benzodiazepines are required for patient management during time of post-injection delirium/sedation syndrome, careful evaluation of clinical status for excessive sedation and cardiorespiratory depression is recommended.

5.3 Elderly Patients with Dementia-Related Psychosis
Increased Mortality
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ZYPREXA RELPRES is not approved for the treatment of patients with dementia-related psychosis [see Boxed Warning, Warnings and Precautions (5.16), and Patient Counseling Information (17.3)].

ZYPREXA RELPRES (olanzapine)
For Extended Release Injectable Suspension

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ZYPREXA RELPRES (olanzapine)
For Extended Release Injectable Suspension
In placebo-controlled oral olanzapine clinical trials of elderly patients with dementia-related psychosis, the incidence of death in olanzapine-treated patients was significantly greater than placebo-treated patients (3.3% vs. 1.5%, respectively).

Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, were reported in patients in trials of oral olanzapine in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of cerebrovascular adverse events in patients treated with oral olanzapine compared to patients treated with placebo. ZYPREXA RELPREVV is not approved for the treatment of patients with dementia-related psychosis [see Boxed Warning and Patient Counseling Information (17.2)].

5.4 Suicide
The possibility of a suicide attempt is inherent in schizophrenia, and close supervision of high-risk patients should accompany drug therapy.

5.5 Neuroleptic Malignant Malignant Syndrome (NMS)
A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs, including olanzapine. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to exclude cases where the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal symptoms and signs (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever, and primary central nervous system pathology.

The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for NMS.

If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered and tolerability with oral olanzapine should be established prior to initiating treatment with ZYPREXA RELPREVV [see Dosage and Administration (2.1)]. The patient should be carefully monitored, since recurrences of NMS have been reported [see Patient Counseling Information (17.4)].

5.6 Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported with olanzapine exposure. DRESS may present with a cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, fever, and/or lymphadenopathy with systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and/or pericarditis. DRESS is sometimes fatal. Discontinue ZYPREXA RELPREVV if DRESS is suspected [see Patient Counseling Information (17.5)].

5.7 Metabolic Changes
Atypical antipsychotic drugs have been associated with metabolic changes including hyperglycemia, dyslipidemia, and weight gain. Metabolic changes may be associated with increased cardiovascular/cerebrovascular risk. Olanzapine’s specific metabolic profile is presented below.

Hyperglycemia and Diabetes Mellitus
Physicians should consider the risks and benefits when prescribing olanzapine to patients with an established diagnosis of diabetes mellitus, or having borderline increased blood glucose level (fasting 100-126 mg/dL, nonfasting 140-200 mg/dL). Patients taking olanzapine should be monitored regularly for worsening of glucose control. Patients starting treatment with olanzapine should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug [see Patient Counseling Information (17.6)].

Hyperglycemia, in some cases extreme and associated with ketoadiposis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including olanzapine. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse reactions in patients treated with the atypical antipsychotics. While relative risk estimates are inconsistent, the association between atypical antipsychotics and increases in glucose levels appears to fall on a continuum and atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug [see Patient Counseling Information (17.6)].

Mean increases in blood glucose have been observed in patients treated (median exposure of 9.2 months) with olanzapine in phase 1 of the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE). The mean increase in serum glucose (fasting and nonfasting samples) from baseline to the average of the highest 2 serum concentrations was 15.0 mg/dL.

In a study of healthy volunteers, subjects who received olanzapine (N=22) for 3 weeks had a mean increase compared to baseline in fasting blood glucose of 2.3 mg/dL. Placebo-treated subjects (N=19) had a mean increase in fasting blood glucose compared to baseline of 0.34 mg/dL.

Olanzapine Monotherapy in Adults — In an analysis of 5 placebo-controlled adult olanzapine monotherapy studies with a median treatment duration of approximately 3 weeks, olanzapine was associated with a greater mean change in fasting glucose levels compared to placebo (2.76 mg/dL versus 0.17 mg/dL). The difference in mean changes between olanzapine and placebo was greater in patients with evidence of glucose dysregulation at baseline (patients diagnosed with diabetes mellitus or related adverse reactions, patients treated with anti-diabetic agents, patients with a baseline random glucose level >200 mg/dL, and/or a baseline fasting glucose level >126 mg/dL).

Olanzapine-treated patients had a greater mean HbA1c, increase from baseline of 0.04% (median exposure 21 days), compared to a mean HbA1c decrease of 0.06% in placebo-treated subjects (median exposure 17 days).

In an analysis of 8 placebo-controlled studies (median treatment exposure 4-5 weeks), 6.1% of olanzapine-treated subjects (N=850) had treatment-emergent glycosuria compared to 2.8% of placebo-treated subjects (N=599). Table 2 shows short-term and long-term changes in fasting glucose levels from adult olanzapine monotherapy studies.

**Table 2: Changes in Fasting Glucose Levels from Adult Olanzapine Monotherapy Studies**

<table>
<thead>
<tr>
<th>Laboratory Analyte</th>
<th>Category Change (at least once) from Baseline</th>
<th>Treatment</th>
<th>N</th>
<th>Patients</th>
<th>N</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Glucose</td>
<td>Normal to High (&lt;100 mg/dL to ≥126 mg/dL)</td>
<td>Olanzapine</td>
<td>543</td>
<td>2.2%</td>
<td>345</td>
<td>12.8%</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>293</td>
<td>3.4%</td>
<td>NA*</td>
<td>NA*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Borderline to High (≥100 mg/dL and &lt;126 mg/dL to ≥126 mg/dL)</td>
<td>Placebo</td>
<td>96</td>
<td>11.5%</td>
<td>NA*</td>
<td>NA*</td>
</tr>
</tbody>
</table>

*Not Applicable.*

The mean change in fasting glucose for patients exposed at least 48 weeks was 4.2 mg/dL (N=487). In analyses of patients who completed 9-12 months of olanzapine therapy, mean change in fasting and nonfasting glucose levels continued to increase over time.

Olanzapine Monotherapy in Adolescents — The safety and efficacy of ZYPREXA RELPREVV have not been established in patients under the age of 18 years.

In an analysis of 3 placebo-controlled oral olanzapine monotherapy studies of adolescent patients (13-17 years), including those with schizophrenia (6 weeks) or bipolar I disorder (manic or mixed episodes) (3 weeks), olanzapine was associated with a greater mean change from baseline in fasting glucose levels compared to placebo (2.68 mg/dL versus 2.59 mg/dL). The mean change in fasting glucose for adolescents exposed at least 24 weeks was 3.1 mg/dL (N=121). Table 3 shows short-term and long-term changes in fasting blood glucose from adolescent oral olanzapine monotherapy studies.

**Table 3: Changes in Fasting Glucose Levels from Adolescent Oral Olanzapine Monotherapy Studies**

<table>
<thead>
<tr>
<th>Laboratory Analyte</th>
<th>Category Change (at least once) from Baseline</th>
<th>Treatment</th>
<th>N</th>
<th>Patients</th>
<th>N</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Glucose</td>
<td>Normal to High (&lt;100 mg/dL to ≥126 mg/dL)</td>
<td>Olanzapine</td>
<td>124</td>
<td>0%</td>
<td>108</td>
<td>0.9%</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>53</td>
<td>1.9%</td>
<td>NA*</td>
<td>NA*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Borderline to High (≥100 mg/dL and &lt;126 mg/dL to ≥126 mg/dL)</td>
<td>Placebo</td>
<td>14</td>
<td>14.3%</td>
<td>13</td>
<td>23.1%</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>13</td>
<td>0%</td>
<td>NA*</td>
<td>NA*</td>
<td></td>
</tr>
</tbody>
</table>

*Not Applicable.*

Dyslipidemia
Undesirable alterations in lipids have been observed with olanzapine use. Clinical monitoring, including baseline and periodic follow-up lipid evaluations in patients using olanzapine, is recommended [see Patient Counseling Information (17.7)].

Clincially significant, and sometimes very high (>500 mg/dL), elevations in triglyceride levels have been observed with olanzapine use. Modest mean increases in total cholesterol have also been seen with olanzapine use.

Olanzapine Monotherapy in Adults — In an analysis of 5 placebo-controlled olanzapine monotherapy studies with treatment duration up to 12 weeks, olanzapine-treated patients had increases from baseline in mean fasting total cholesterol, LDL cholesterol, and triglycerides of 5.3 mg/dL, 3.0 mg/dL, and 20.8 mg/dL respectively compared to decreases from baseline in mean fasting total cholesterol, LDL cholesterol, and triglycerides of 6.1 mg/dL, 4.3 mg/dL, and 10.7 mg/dL for placebo-treated patients. For fasting HDL cholesterol, no clinically meaningful differences were observed between olanzapine-treated patients and placebo-treated patients.

Mean increases in fasting lipid values (total cholesterol, LDL cholesterol, and triglycerides) were greater in patients without evidence of lipid dysregulation at baseline, where lipid dysregulation was defined as patients diagnosed with dyslipidemia or related adverse reactions, patients treated with lipid lowering agents, or patients with high baseline lipid levels.

ZYPREXA RELPREVV (olanzapine)
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In long-term studies (at least 48 weeks), patients had increases from baseline in mean fasting total cholesterol, LDL cholesterol, and triglycerides of 5.6 mg/dL, 2.5 mg/dL, and 18.7 mg/dL, respectively, and a mean decrease in fasting HDL cholesterol of 0.16 mg/dL. In an analysis of patients who completed 12 months of therapy, the mean nonfasting total cholesterol did not increase further after approximately 4-6 months.

The proportion of patients who had changes (at least once) in total cholesterol, LDL cholesterol or triglycerides from normal or borderline to high, or changes in HDL cholesterol did not increase further after approximately 4-6 months.

Increases in fasting lipids were observed in adolescents (13-17 years), including those with schizophrenia (6 weeks) or bipolar I disorder (manic or mixed episodes) (3 weeks), olanzapine-treated adolescents had increases from baseline in mean fasting total cholesterol, LDL cholesterol, and triglycerides of 12.9 mg/dL, 6.5 mg/dL, and 28.4 mg/dL, respectively, compared to increases from baseline in mean fasting total cholesterol and LDL cholesterol of 1.3 mg/dL and 1.0 mg/dL, and a decrease in triglycerides of 1.1 mg/dL for placebo-treated adolescents. For fasting HDL cholesterol, no clinically meaningful differences were observed between olanzapine-treated adolescents and placebo-treated adolescents.

In long-term studies (at least 24 weeks), adolescents had increases from baseline in mean fasting total cholesterol, LDL cholesterol, and triglycerides of 5.5 mg/dL, 5.4 mg/dL, and 20.5 mg/dL, respectively, and a mean decrease in fasting HDL cholesterol of 4.5 mg/dL. Table 5 shows categorical changes in fasting lipids values in adolescents.

### Table 4: Changes in Fasting Lipids Values from Adult Olanzapine Monotherapy Studies

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Category Change (at least once) from Baseline</th>
<th>Treatment Arm</th>
<th>Up to 12 weeks exposure</th>
<th>At least 48 weeks exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fasting Triglycerides</strong></td>
<td>Increase by ≥50 mg/dL</td>
<td>Olanzapine 745</td>
<td>39.6%</td>
<td>487</td>
</tr>
<tr>
<td></td>
<td>Normal to High (&lt;150 mg/dL to &gt;200 mg/dL)</td>
<td>Olanzapine 457</td>
<td>9.2%</td>
<td>293</td>
</tr>
<tr>
<td></td>
<td>Borderline to High (≥150 mg/dL and &lt;200 mg/dL to &gt;200 mg/dL)</td>
<td>Olanzapine 135</td>
<td>39.3%</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>Increase by ≥40 mg/dL</td>
<td>Olanzapine 745</td>
<td>21.6%</td>
<td>489</td>
</tr>
<tr>
<td></td>
<td>Normal to High (&lt;200 mg/dL to &gt;240 mg/dL)</td>
<td>Olanzapine 392</td>
<td>2.8%</td>
<td>283</td>
</tr>
<tr>
<td></td>
<td>Borderline to High (≥200 mg/dL and &lt;240 mg/dL to &gt;240 mg/dL)</td>
<td>Olanzapine 112</td>
<td>12.5%</td>
<td>NAa</td>
</tr>
<tr>
<td><strong>Fasting Total Cholesterol</strong></td>
<td>Increase by ≥30 mg/dL</td>
<td>Olanzapine 536</td>
<td>23.7%</td>
<td>483</td>
</tr>
<tr>
<td></td>
<td>Normal to High (&lt;100 mg/dL to ≤160 mg/dL)</td>
<td>Olanzapine 154</td>
<td>0%</td>
<td>123</td>
</tr>
<tr>
<td></td>
<td>Borderline to High (≥100 mg/dL and &lt;160 mg/dL to ≥160 mg/dL)</td>
<td>Olanzapine 302</td>
<td>10.6%</td>
<td>284</td>
</tr>
<tr>
<td></td>
<td>Increase by ≥20 mg/dL</td>
<td>Olanzapine 402</td>
<td>9.5%</td>
<td>948</td>
</tr>
<tr>
<td></td>
<td>Normal to High (&lt;110 mg/dL to ≤130 mg/dL)</td>
<td>Olanzapine 82</td>
<td>1.2%</td>
<td>65</td>
</tr>
<tr>
<td></td>
<td>Borderline to High (≥110 mg/dL and &lt;130 mg/dL to ≥130 mg/dL)</td>
<td>Olanzapine 65</td>
<td>20.0%</td>
<td>NAa</td>
</tr>
<tr>
<td><strong>Fasting LDL Cholesterol</strong></td>
<td>Increase by ≥10 mg/dL</td>
<td>Olanzapine 173</td>
<td>8.1%</td>
<td>134</td>
</tr>
<tr>
<td></td>
<td>Normal to High (&lt;100 mg/dL to ≤160 mg/dL)</td>
<td>Olanzapine 302</td>
<td>10.6%</td>
<td>284</td>
</tr>
</tbody>
</table>

*Not Applicable.*

### Table 5: Changes in Fasting Lipids Values from Adolescent Oral Olanzapine Monotherapy Studies

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Category Change (at least once) from Baseline</th>
<th>Treatment Arm</th>
<th>Up to 6 weeks exposure</th>
<th>At least 24 weeks exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fasting Triglycerides</strong></td>
<td>Increase by ≥50 mg/dL</td>
<td>Olanzapine 138</td>
<td>37.0%</td>
<td>122</td>
</tr>
<tr>
<td></td>
<td>Normal to High (&lt;90 mg/dL to &gt;130 mg/dL)</td>
<td>Olanzapine 67</td>
<td>26.9%</td>
<td>66</td>
</tr>
<tr>
<td></td>
<td>Borderline to High (≥90 mg/dL and &lt;130 mg/dL to &gt;130 mg/dL)</td>
<td>Olanzapine 37</td>
<td>59.5%</td>
<td>31</td>
</tr>
<tr>
<td><strong>Fasting Total Cholesterol</strong></td>
<td>Increase by ≥40 mg/dL</td>
<td>Olanzapine 138</td>
<td>14.5%</td>
<td>122</td>
</tr>
<tr>
<td></td>
<td>Normal to High (&lt;170 mg/dL to ≥200 mg/dL)</td>
<td>Olanzapine 87</td>
<td>6.9%</td>
<td>78</td>
</tr>
<tr>
<td></td>
<td>Borderline to High (≥170 mg/dL and &lt;200 mg/dL to ≥200 mg/dL)</td>
<td>Olanzapine 36</td>
<td>38.9%</td>
<td>33</td>
</tr>
<tr>
<td><strong>Fasting LDL Cholesterol</strong></td>
<td>Increase by ≥30 mg/dL</td>
<td>Olanzapine 137</td>
<td>17.5%</td>
<td>121</td>
</tr>
<tr>
<td></td>
<td>Normal to High (&lt;110 mg/dL to ≤130 mg/dL)</td>
<td>Olanzapine 98</td>
<td>5.1%</td>
<td>92</td>
</tr>
<tr>
<td></td>
<td>Borderline to High (≥110 mg/dL and &lt;130 mg/dL to ≥130 mg/dL)</td>
<td>Olanzapine 29</td>
<td>48.3%</td>
<td>21</td>
</tr>
</tbody>
</table>

*Not Applicable.*

### Weight Gain

Potential consequences of weight gain should be considered prior to starting olanzapine. Patients receiving olanzapine should receive regular monitoring of weight [see Patient Counseling Information (17.8)].

**Olanzapine Monotherapy in Adults** — In an analysis of 13 placebo-controlled olanzapine monotherapy studies, olanzapine-treated patients gained an average of 2.6 kg (5.7 lb) compared to an average 0.3 kg (0.6 lb) weight loss in placebo-treated patients with a median exposure of 6 weeks; 22.2% of olanzapine-treated patients gained at least 7% of their baseline weight, compared to 3% of placebo-treated patients, with a median exposure to event of 8 weeks; 4.2% of olanzapine-treated patients gained at least 15% of their baseline weight, compared to 0.3% of placebo-treated patients, with a median exposure to event of 12 weeks. Clinically significant weight gain was observed across all baseline Body Mass Index (BMI) categories. Discontinuation due to weight gain occurred in 0.2% of olanzapine-treated patients and in 0% of placebo-treated patients.

In long-term studies (at least 48 weeks), the mean weight gain was 5.6 kg (12.3 lb) (median exposure of 573 days, N=2021). The percentages of patients who gained at least 7%, 15%, or 25% of their baseline body weight with long-term exposure were 34%, 32%, and 12%, respectively. Discontinuation due to weight gain occurred in 0.4% of olanzapine-treated patients following at least 48 weeks of exposure.

Table 6 includes data on adult weight gain with olanzapine pooled from 86 clinical trials. The data in each column represent data for those patients who completed treatment periods of the durations specified.

### Table 6: Weight Gain with Olanzapine Use in Adults

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Category Change (at least once) from Baseline</th>
<th>Up to 6 weeks exposure</th>
<th>At least 6 weeks exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Treatment Arm</td>
<td>N Patients</td>
<td>N Patients</td>
</tr>
<tr>
<td>Increase by ≥15 kg</td>
<td>Olanzapine 367</td>
<td>26.0%</td>
<td>26.0%</td>
</tr>
<tr>
<td></td>
<td>Placebo 23</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Increase by ≥30 kg</td>
<td>Olanzapine 132</td>
<td>26.0%</td>
<td>26.0%</td>
</tr>
<tr>
<td></td>
<td>Placebo 22</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Not Applicable.*

In phase 1 of the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE), over a median exposure of 9.2 months, the mean increase in triglycerides in patients taking olanzapine was 40.5 mg/dL. In phase 1 of CATIE, the mean increase in total cholesterol was 9.4 mg/dL. Dose group differences with respect to increases in fasting triglycerides have been observed. In a 24-week randomized, double-blind, fixed-dose study with ZYPREXA RELPREV, statistically significant differences among dose groups have been observed for fasting triglycerides. Incidence of changes from normal to high levels of fasting triglycerides at any time during the trial indicated significant differences between the highest dose group (500 mg/2 weeks, 24.5% [13/53]) and the lower dose groups (150 mg/2 weeks, 6.5% [13/208]; 300 mg/2 weeks, 2.8% [6/208]).
Dose group differences with respect to weight gain have been observed in some studies. In a 24-week randomized, double-blind, fixed-dose study with ZYPREXA RELPREVV, mean baseline-to-endpoint increase in weight (150 mg/2 weeks, n=142: 0.67 kg; 405 mg/4 weeks, n=315: 0.89 kg; 300 mg/2 weeks, n=140: 1.70 kg) was observed with significant differences between the lowest and highest dose groups (150 mg vs 300 mg/2 weeks). In a single 8-week randomized, double-blind, fixed-dose study comparing 10 (N=199), 20 (N=200) and 40 (N=200) mg/day of oral olanzapine in adult patients with schizophrenia or schizoaffective disorder, mean baseline to endpoint increase in weight (10 mg/day: 1.9 kg; 20 mg/day: 2.3 kg; 40 mg/day: 3 kg) was observed with significant differences between 10 vs 40 mg/day.

Olanzapine Monotherapy in Adolescents — The safety and efficacy of ZYPREXA RELPREVV have not been established in patients under the age of 18 years. Mean increase in weight in adolescents was greater than in adults. In 4 placebo-controlled trials, discontinuation due to weight gain occurred in 1% of olanzapine-treated patients, compared to 0% of placebo-treated patients.

### Table 7: Weight Gain with Oral Olanzapine Use in Adolescents from 4 Placebo-Controlled Trials

<table>
<thead>
<tr>
<th>Olanzapine-treated patients</th>
<th>Placebo-treated patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean change in body weight from baseline (median exposure = 3 weeks)</td>
<td>4.6 kg (10.1 lb)</td>
</tr>
<tr>
<td>Percentage of patients who gained at least 7% of baseline body weight</td>
<td>40.6% (median exposure to 7% = 4 weeks)</td>
</tr>
<tr>
<td>Percentage of patients who gained at least 15% of baseline body weight</td>
<td>7.1% (median exposure to 15% = 19 weeks)</td>
</tr>
</tbody>
</table>

In long-term studies (at least 24 weeks), the mean weight gain was 11.2 kg (24.6 lb); (median exposure of 201 days, N=179). The percentages of adolescents who gained at least 7%, 15%, or 25% of their baseline body weight with long-term exposure were 89%, 55%, and 29%, respectively. Among adolescent patients, mean weight gain by baseline BMI category was 11.5 kg (25.3 lb), 12.1 kg (26.6 lb), and 12.7 kg (27.9 lb), respectively, for normal (N=106), overweight (N=26) and obese (N=17). Discontinuation due to weight gain occurred in 2.2% of olanzapine-treated patients following at least 24 weeks of exposure. Table 8 shows data on adolescent weight gain with olanzapine pooled from 6 clinical trials. The data in each column represent data for those patients who completed treatment periods of the durations specified. Little clinical trial data is available on weight gain in adolescents with olanzapine beyond 6 months of treatment.

### Table 8: Weight Gain with Olanzapine Use in Adolescents

<table>
<thead>
<tr>
<th>Amount Gained (kg)</th>
<th>6 Weeks (N=243) (%)</th>
<th>6 Months (N=191) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤0</td>
<td>2.9</td>
<td>2.1</td>
</tr>
<tr>
<td>0 to ≤5 (0-11 lb)</td>
<td>47.3</td>
<td>24.6</td>
</tr>
<tr>
<td>&gt;5 to ≤10 (11-22 lb)</td>
<td>42.4</td>
<td>26.7</td>
</tr>
<tr>
<td>&gt;10 to ≤15 (22-33 lb)</td>
<td>5.8</td>
<td>22.0</td>
</tr>
<tr>
<td>&gt;15 to ≤20 (33-44 lb)</td>
<td>0.8</td>
<td>12.6</td>
</tr>
<tr>
<td>&gt;20 to ≤25 (44-55 lb)</td>
<td>0.8</td>
<td>9.4</td>
</tr>
<tr>
<td>&gt;25 to ≤30 (55-66 lb)</td>
<td>0</td>
<td>2.1</td>
</tr>
<tr>
<td>&gt;30 to ≤35 (66-77 lb)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>&gt;35 to ≤40 (77-88 lb)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>&gt;40 (≥88 lb)</td>
<td>0</td>
<td>0.5</td>
</tr>
</tbody>
</table>

### 5.8 Tardive Dyskinesia

A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses or may even arise after discontinuation of treatment.

There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

Given these considerations, olanzapine should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients (1) who suffer from a chronic illness that is known to respond to antipsychotic drugs, and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.

If signs and symptoms of tardive dyskinesia appear in a patient on olanzapine, drug discontinuation should be considered. However, some patients may require treatment with olanzapine despite the presence of the syndrome.

### 5.9 Orthostatic Hypotension

ZYPREXA RELPREVV may induce orthostatic hypotension associated with dizziness, tachycardia, bradycardia and, in some patients, syncope, probably reflecting its α1-adrenergic antagonistic properties [see Patient Counseling Information (17.9)]. Syncope-related adverse reactions were reported in 0.1% of patients treated with ZYPREXA RELPREVV in clinical studies.

From an analysis of the vital sign data in an integrated database of 41 completed clinical studies in adult patients treated with oral olanzapine, orthostatic hypotension was reported in ≥2% (1277/6033) of patients.

Olanzapine should be used with particular caution in patients with known cardiovascular disease (history of myocardial infarction or ischemia, heart failure, or conduction abnormalities), cerebrovascular disease, and conditions which would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications) where the occurrence of syncope, or hypotension and/or bradycardia might put the patient at increased medical risk. For patients in this population who have never taken oral olanzapine, tolerability should be established with oral olanzapine prior to initiating treatment with ZYPREXA RELPREVV [see Dosage and Administration (2.1)].

Caution is necessary in patients who receive treatment with other drugs having effects that can induce hypotension, bradycardia, respiratory or central nervous system depression [see Drug Interactions (7)].

### 5.10 Falls

ZYPREXA RELPREVV may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls and, consequently, fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments when initiating antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.

### 5.11 Leukopenia, Neutropenia, and Agranulocytosis

#### Table 8: Weight Gain with Olanzapine Use in Adolescents

<table>
<thead>
<tr>
<th>Amount Gained (kg)</th>
<th>6 Weeks (N=243) (%)</th>
<th>6 Months (N=191) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤0</td>
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<td>2.1</td>
</tr>
<tr>
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</tr>
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<td>26.7</td>
</tr>
<tr>
<td>&gt;10 to ≤15 (22-33 lb)</td>
<td>5.8</td>
<td>22.0</td>
</tr>
<tr>
<td>&gt;15 to ≤20 (33-44 lb)</td>
<td>0.8</td>
<td>12.6</td>
</tr>
<tr>
<td>&gt;20 to ≤25 (44-55 lb)</td>
<td>0.8</td>
<td>9.4</td>
</tr>
<tr>
<td>&gt;25 to ≤30 (55-66 lb)</td>
<td>0</td>
<td>2.1</td>
</tr>
<tr>
<td>&gt;30 to ≤35 (66-77 lb)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>&gt;35 to ≤40 (77-88 lb)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>&gt;40 (≥88 lb)</td>
<td>0</td>
<td>0.5</td>
</tr>
</tbody>
</table>

### 5.12 Dysphagia

Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer’s disease. Olanzapine is not approved for the treatment of patients with Alzheimer’s disease.

### 5.13 Seizures

During premarketing testing of ZYPREXA RELPREVV, seizures occurred in 0.15% of patients. During premarketing testing of oral olanzapine, seizures occurred in 0.9% of olanzapine-treated patients. There were confounding factors that may have contributed to the occurrence of seizures in many of these cases.

Olanzapine should be used cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold, e.g., Alzheimer’s dementia. Olanzapine is not approved for the treatment of patients with Alzheimer’s disease.

### 5.14 Potential for Cognitive and Motor Impairment

Sedation was a commonly reported adverse reaction associated with ZYPREXA RELPREVV treatment, occurring at an incidence of 6% in ZYPREXA RELPREVV patients compared to 2% in placebo patients. Somnolence and sedation adverse reactions led to discontinuation in 0.6% of patients in the premarketing ZYPREXA RELPREVV database.

Since olanzapine has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that olanzapine therapy does not affect them adversely. However, due to the risk of post-injection delirium/sedation syndrome after each injection, patients should not drive or operate heavy machinery for the remainder of the day of each injection [see Dosage and Administration (2.1), Warnings and Precautions (5.1), and Patient Counseling Information (17.10)].

### 5.15 Body Temperature Regulation

Disruption of the body’s ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing ZYPREXA RELPREVV for patients who will be experiencing conditions which may contribute to an elevation in core body temperature, e.g., exercising strenuously, exposure to extreme heat, receiving concomitant ZYPREXA RELPREVV (olanzapine)

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ZYPR-0007-USPI-20181106
medication with anticholinergic activity, or being subject to dehydration [see Patient Counseling Information (17.11)].

5.16 Use in Patients with Concomitant Illness

Experience with ZYPREXA RELPREVV in patients with concomitant systemic illnesses is limited [see Clinical Pharmacology (12.3)].

Olanzapine exhibits in vitro muscarinic receptor affinity. In premarketing clinical trials with oral olanzapine, olanzapine was associated with constipation, dry mouth, and tachycardia, all adverse reactions possibly related to cholinergic antagonism. Such adverse reactions were not often the basis for discontinuations from olanzapine, but olanzapine should be used with caution in patients with clinically significant prostatic hypertrophy, narrow angle glaucoma, or a history of paralytic ileus or related conditions.

In 5 placebo-controlled studies of oral olanzapine in elderly patients with dementia-related psychosis (n=1184), the following treatment-emergent adverse reactions were reported in olanzapine-treated patients at an incidence of at least 2% and significantly greater than placebo-treated patients: falls, somnolence, peripheral edema, abnormal gait, urinary incontinence, edema, weight gain, asthenia, pneumonia, dry mouth, visual hallucinations. The rate of discontinuation due to adverse reactions was significantly greater with oral olanzapine than placebo (13% vs 7%). Elderly patients with dementia-related psychosis treated with olanzapine are at an increased risk of death compared to placebo. Olanzapine is not approved for the treatment of patients with dementia-related psychosis [see Boxed Warning, Warnings and Precautions (5.3), and Patient Counseling Information (17.3)].

Olanzapine has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical studies. Because of the risk of orthostatic hypotension with olanzapine, caution should be observed in cardiac patients [see Warnings and Precautions (5.9)].

5.17 Hyperprolactinemia

As with other drugs that antagonize dopamine D2 receptors, olanzapine elevates prolactin levels, and the elevation persists during chronic administration. Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male subjects.

Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. As is common with compounds which increase prolactin release, an increase in mammary gland neoplasia was observed in the oral olanzapine carcinogenicity studies conducted in mice and rats [see Nonclinical Toxicology (13.1)].

Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorogenesis in humans; the available evidence is considered too limited to be conclusive at this time.

In placebo-controlled olanzapine clinical studies (up to 12 weeks), changes from normal to high in prolactin concentrations were observed in 30% of adults treated with olanzapine as compared to 10.5% of adults treated with placebo. In a pooled analysis from clinical studies including 8136 adults treated with olanzapine, potentially associated clinical manifestations included menstrual-related events1 (2% [150/8136] of females) and males), and breast-related events2 (0.7% [23/3240] of females, 0.2% [9/4896] of males).

In placebo-controlled olanzapine monotherapy studies in adolescent patients (up to 6 weeks) with schizophrenia or bipolar I disorder (manic or mixed episodes), changes from normal to high in prolactin concentrations were observed in 47% of olanzapine-treated patients compared to 7% of placebo-treated patients. In a pooled analysis from clinical trials including 454 adolescents treated with olanzapine, potentially associated clinical manifestations included menstrual-related events1 (1% [2/168] of females), sexual function-related events2 (0.7% [3/454] of females and males), and breast-related events2 (2% [3/168] of females, 2% [7/2986] of males) [see Use in Specific Populations (8.4)].

1 Based on a search of the following terms: amenorrhea, hypogonadism, menstruation delayed, and oligomenorrhea.

2 Based on a search of the following terms: anorgasmia, delayed ejaculation, erectile dysfunction, decreased libido, loss of libido, abnormal orgasm, and sexual dysfunction.

3 Based on a search of the following terms: breast discharge, enlargement or swelling, galactorrhea, gynecomastia, and lactation disorder.

Dose group differences with respect to prolactin elevation have been observed in some studies. In a 24-week randomized, double-blind, fixed-dose study with ZYPREXA RELPREVV, statistically significant differences among dose groups were observed for prolactin levels, with a mean baseline-to-endpoint increase observed in the highest dose group of 300 mg/2 weeks, n=115: 35.77 ng/ml (mean) relative to mean decreases in the lower dose groups (150 mg/2 weeks, n=109: -5.61 ng/ml; 405 mg/4 weeks, n=259: -2.76 ng/ml). In a single 8-week randomized, double-blind, fixed-dose study comparing 10 mg (N=199), 20 mg (N=200) and 40 mg (N=200) mg/day of oral olanzapine in adult patients with schizophrenia or schizoaffective disorder, incidence of prolactin elevation >24.2 mg/ml (female) >18.77 mg/ml (male) at any time during the trial (10 mg/day: 2%, 20 mg/day: 42.7%, 40 mg/day: 61.1%) indicated significant differences between 10 vs 40 mg/day and 20 vs 40 mg/day.

5.18 Laboratory Tests

Fasting blood glucose testing and lipid profile at the beginning of, and periodically during, treatment is recommended [see Warnings and Precautions (5.7) and Patient Counseling Information (17.6; 17.7)].

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

The information below for ZYPREXA RELPREVV is derived primarily from a clinical trial database consisting of 21658 patients with approximately 1948 years of exposure to ZYPREXA RELPREVV. This database includes safety data from 6 open-label studies and 2 double-blind comparator studies, conducted in patients with schizophrenia or schizoaffective disorder. Additionally, data obtained from patients treated with oral olanzapine are also presented. Adverse reactions were assessed by the collection of adverse reactions, vital signs, weights, laboratory analyses, ECGs, and the results of physical and ophthalmologic examinations. In the tables and tabulations that follow for ZYPREXA RELPREVV, the MedDRA terminology has been used to classify adverse reactions. Data obtained from oral olanzapine studies was reported using the COSTART and MedDRA dictionaries.

The stated frequencies of adverse reactions represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse reaction of the type listed. A reaction was considered treatment emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. Reactions listed elsewhere in labeling may not be repeated below. The entire label should be read to gain a complete understanding of the safety profile of ZYPREXA RELPREVV.

The prescriber should be aware that the figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the adverse reaction incidence in the population studied.

Adverse Reactions Associated with Discontinuation of Treatment in a Short-Term, Placebo-Controlled Trial

Overall, there was no difference in the incidence of discontinuation due to adverse reactions between ZYPREXA RELPREVV (4%; 13/306 patients) and placebo (5%; 5/98) in an 8-week trial.

Commonly Observed Adverse Reactions in a Short-Term, Placebo-Controlled Trial

In an 8-week trial, treatment-emergent adverse reactions with an incidence of 5% or greater in at least one of the ZYPREXA RELPREVV treatment groups (210 mg/2 weeks, 405 mg/4 weeks, or 500 mg/2 weeks) and greater than placebo were: headache, sedation, weight gain, cough, diarrhea, back pain, nausea, somnolence, dry mouth, nasopharyngitis, increased appetite, and vomiting.

Adverse Reactions Occurring at an Incidence of 2% or More among ZYPREXA RELPREVV-Treated Patients in a Short-Term, Placebo-Controlled Trial

Table 9 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse reactions that occurred in 2% or more of patients treated with ZYPREXA RELPREVV and with incidence greater than placebo who participated in the 8-week, placebo-controlled trial.

Table: 9 Treatment-Emergent Adverse Reactions:
Incidence in a Short-Term, Placebo-Controlled Clinical Trial with ZYPREXA RELPREVV

<table>
<thead>
<tr>
<th>Body System/Adverse Reaction</th>
<th>Placebo (N=98)</th>
<th>ZYPREXA RELPREVV 405 mg/4 wks (N=100)</th>
<th>ZYPREXA RELPREVV 210 mg/2 wks (N=100)</th>
<th>ZYPREXA RELPREVV 300 mg/2 wks (N=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ear and Labyrinth Disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ear pain</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td><strong>Gastrointestinal Disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4</td>
<td>2</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>1</td>
<td>2</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Flatulence</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Nausea</td>
<td>2</td>
<td>5</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Toothache</td>
<td>0</td>
<td>3</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2</td>
<td>6</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td><strong>General Disorders and Administration Site Conditions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Injection site pain</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Pain</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Infections and Infestations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>3</td>
<td>6</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Tooth infection</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Viral infection</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

ZYPREXA RELPREVV (olanzapine)
For Extended Release Injectable Suspension
ZYPR-0007-USPI-20181109

ZYPREXA RELPREVV (olanzapine)
For Extended Release Injectable Suspension
ZYPR-0007-USPI-20181019 PRINTER VERSION 7 OF 15
Table 9: Treatment-Emergent Adverse Reactions: Incidence in a Short-Term, Placebo-Controlled Clinical Trial with ZYPREXA RELPREVV (Cont.)

<table>
<thead>
<tr>
<th>Body System/Adverse Reaction</th>
<th>Placebo (N=98)</th>
<th>ZYPREXA RELPREVV 405 mg/4 wks (N=100)</th>
<th>ZYPREXA RELPREVV 210 mg/2 wks (N=106)</th>
<th>ZYPREXA RELPREVV 300 mg/2 wks (N=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injury, Poisoning and Procedural Complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedural pain</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Investigations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrocardiogram QT-corrected interval prolonged</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Hepatic enzyme increased</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Weight increased</td>
<td>5</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Metabolism and Nutrition Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased appetite</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Musculoskeletal and Connective</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthralgia</td>
<td>0</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Back pain</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Musculoskeletal stiffness</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Dysarthria</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Headache</td>
<td>8</td>
<td>13</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>Sedation</td>
<td>7</td>
<td>13</td>
<td>8</td>
<td>13</td>
</tr>
<tr>
<td>Tremor</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Psychiatric Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal dreams</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Hallucination, auditory</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Restlessness</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>1</td>
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<tr>
<td>Sleep disorder</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Thinking abnormal</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Reproductive System and Breast Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal discharge</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Respiratory, Thoracic and Mediastinal Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Nasal congestion</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Pharyngolaryngeal pain</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Sneezing</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Skin and Subcutaneous Tissue Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acne</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Vascular Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

6.2 Extrapyramidal Symptoms

The following table enumerates the percentage of patients with treatment-emergent extrapyramidal symptoms as assessed by categorical analyses of formal rating scales during acute therapy in a controlled clinical trial comparing oral olanzapine at 3 fixed doses with placebo in the treatment of schizophrenia in a 6-week trial.

Table 10: Treatment-Emergent Extrapyramidal Symptoms Assessed by Rating Scales Incidence in a Fixed Dosage Range, Placebo-Controlled Clinical Trial of Oral Olanzapine in Schizophrenia — Acute Phase

<table>
<thead>
<tr>
<th>Percentage of Patients Reporting Event</th>
<th>Placebo (N=68)</th>
<th>Olanzapine 5 ± 2.5 mg/day (N=65)</th>
<th>Olanzapine 10 ± 2.5 mg/day (N=64)</th>
<th>Olanzapine 15 ± 2.5 mg/day (N=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parkinsonism</td>
<td>13</td>
<td>14</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td>Akathisia</td>
<td>23</td>
<td>16</td>
<td>19</td>
<td>27</td>
</tr>
</tbody>
</table>

The following table enumerates the percentage of patients with treatment-emergent extrapyramidal symptoms as assessed by spontaneously reported adverse reactions during acute therapy in the same controlled clinical trial comparing olanzapine at 3 fixed doses with placebo in the treatment of schizophrenia in a 6-week trial.

Table 11: Treatment-Emergent Extrapyramidal Symptoms Assessed by Adverse Reactions Incidence in a Fixed Dosage Range, Placebo-Controlled Clinical Trial of Oral Olanzapine in Schizophrenia — Acute Phase

<table>
<thead>
<tr>
<th>Percentage of Patients Reporting Event</th>
<th>Placebo (N=68)</th>
<th>Olanzapine 5 ± 2.5 mg/day (N=65)</th>
<th>Olanzapine 10 ± 2.5 mg/day (N=64)</th>
<th>Olanzapine 15 ± 2.5 mg/day (N=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dystonic events</td>
<td>16</td>
<td>15</td>
<td>25</td>
<td>32</td>
</tr>
<tr>
<td>Parkinsonism events</td>
<td>10</td>
<td>8</td>
<td>14</td>
<td>20</td>
</tr>
<tr>
<td>Akathisia events</td>
<td>1</td>
<td>5</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Dyskinetic events</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Residual events</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>

Dystonia, Class Effect: Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, the frequency and severity are greater with high potency and at higher doses of first generation antipsychotic drugs. In general, an elevated risk of acute dystonia may be observed in males and younger age groups receiving antipsychotics; however, events of dystonia have been reported infrequently (<1%) with olanzapine use.

6.3 Other Adverse Reactions

Local Injection Site Reactions

Eleven ZYPREXA RELPREVV-treated patients (3.6%) and 0 placebo-treated patients experienced treatment-emergent injection-related adverse reactions (injection site pain, buttock pain, injection site mass, induration, injection site induration) in the placebo-controlled database. The most frequently occurring treatment-emergent adverse reaction was injection site pain (2.3% ZYPREXA RELPREVV-treated; 0% placebo-treated).

Other Adverse Reactions Observed During the Clinical Trial Evaluation of Olanzapine for Extended-Release Injectable Suspension

Injection site abscess has been reported in clinical trials with ZYPREXA RELPREVV therapy. Isolated cases required surgical intervention.

Commonly Observed Adverse Reactions During the Clinical Trial Evaluation of Olanzapine

In clinical trials of oral olanzapine monotherapy for the treatment of schizophrenia in adult patients, treatment-emergent adverse reactions with an incidence of 5% or greater in the olanzapine treatment arm and at least twice that of placebo were: postural hypotension, constipation, weight gain, dizziness, personality disorder, and akathisia.

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Other Adverse Reactions Observed During the Clinical Trial Evaluation of Oral Olanzapine

Following is a list of treatment-emergent adverse reactions reported by patients treated with oral olanzapine (at multiple doses ≥1 mg/day) in clinical trials. This listing is not intended to include adverse reactions already listed in previous tables or elsewhere in labeling, (G), for which a drug cause was remote, (3), which were so general as to be uninformative, (4), which were not considered to have significant clinical implications, or (5) which occurred at a rate equal to or less than placebo. Reactions are classified by body system using the following definitions: frequent adverse reactions are those occurring in at least 1/100 patients; infrequent adverse reactions are those occurring in 1/100 to 1/1000 patients; rare adverse reactions are those occurring in fewer than 1/1000 patients.

Body as a Whole — Infrequent: chills, face edema, photosensitivity reaction, suicide attempt, Rare: chills and fever, hangover effect, sudden death

Cardiovascular System — Infrequent: carotid sinus accident, vasodilatation

Digestive System — Infrequent: abdominopelvic distension, nausea and vomiting, tongue edema; Rare: ileus, intestinal obstruction, liver fatty deposit.

Hemic and Lymphatic System — Infrequent: thrombocytopenia.

Metabolic and Nutritional Disorders — Frequent: alkaline phosphatase increased; Infrequent: bilirubinuria, hypoglycemia.

Musculoskeletal System — Rare: osteoporosis.

Nervous System — Infrequent: ataxia, dysarthria, libido decreased, stupor;

Rare: myoclonus.

Urogenital System — Infrequent: amenorrhea, breast pain, decreased menstruation, impotence, increased menstruation, menorrhagia, metrorrhagia, polyuria, urinary frequency, urinary retention, urinary urgency, urination impaired.

1 These terms represent serious adverse events but do not meet the definition for adverse drug reactions. They are included here because of their seriousness.

2 Adjusted for gender.

Vital Signs and Laboratory Studies

Laboratory Changes

ZYPREXA RELPREVV in Adults: Statistically significant within group mean changes for ZYPREXA RELPREVV, which were also significantly different from placebo, were observed for the following: eosinophils, monocytes, cholesterol, low-density lipoprotein (LDL), triglycerides, and direct bilirubin. There were no statistically significant differences between ZYPREXA RELPREVV and placebo in the incidence of potentially clinically significant changes in any of the laboratory values studied.

Statistically significant within group mean changes for ZYPREXA RELPREVV, which were also significantly different for oral olanzapine (in a 24-week double-blind study), were observed for the following: gamma-glutamyltransferase (GGT) and sodium. From an analysis of the laboratory data in an integrated database of 41 completed clinical trials involving adult patients treated with oral olanzapine, high GGT levels were recorded in ≥1% (88/5245) of patients.

Statistically significant differences were observed between ZYPREXA RELPREVV and oral olanzapine for the incidence of treatment-emergent low platelet count (0% ZYPREXA RELPREVV vs 0.7% for oral olanzapine). There was a statistically significant difference between ZYPREXA RELPREVV and oral olanzapine in potentially clinically significant changes for high uric acid levels (≥3 times the upper limit of normal). From an analysis of the laboratory data in an integrated database of 41 completed clinical studies in adult patients treated with oral olanzapine, elevated uric acid was recorded in 2.3% (171/6481) of patients.

Olanzapine Monotherapy in Adults: An assessment of the premarketing experience for oral olanzapine revealed an association with asymptomatic increases in ALT, AST, and GGT. Within the original premarketing database of about 2400 adult patients with baseline ALT <90 IU/L, the incidence of ALT elevations >200 IU/L was 2% (50/2381). None of these patients experienced jaundice or other symptoms attributable to liver impairment and most had transient changes that tended to normalize while ZYPREXA RELPREVV treatment was continued.

From an analysis of the laboratory data in an integrated database of 41 completed clinical studies in adult patients treated with oral olanzapine, elevated uric acid was recorded in ≤3% (171/6481) of patients.

Olanzapine administration was also associated with increases in serum prolactin [see Warnings and Precautions (5.17)], with an asymptomatic elevation of the eosinophil count in 0.3% of patients, and with an increase in CPK.

ECG Changes: Comparison of ZYPREXA RELPREVV and oral olanzapine, in a 24 week study, revealed no significant differences on ECG changes. Between-group comparisons for pooled placebo-controlled trials revealed no significant oral olanzapine/placebo differences in the proportions of patients experiencing potentially important changes in ECG parameters, including QT, QTc, and PR intervals. Olanzapine use was associated with a mean increase in heart rate of 1.6 beats per minute which was similar to placebo. No change among placebo patients. The slight tendency to tachycardia may be related to olanzapine’s potential for inducing orthostatic changes [see Warnings and Precautions (5.11)].

6.4 Postmarketing Experience

Adverse reactions reported since marketing introduction that were temporally (but not necessarily causally) related to ZYPREXA therapy include the following: allergic reaction (e.g., urticaria), angioedema, pruritus or urticaria, cholestatic, or mixed liver injury, diabetic coma, diabetic ketoacidosis, discontinuation reaction (diaphoresis, nausea, or vomiting), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), hepatitis, jaundice, neutropenia, pancreatitis, priapism, rash, restless legs syndrome, rhabdomyolysis, stuttering,2 and venous thromboembolic events (including pulmonary embolism and deep venous thrombosis). Random cholesterol levels of ≥240 mg/dL and random triglyceride levels of ≥1000 mg/dL have been reported. Additionally, injection site abscesses have been reported in postmarketing reports with ZYPREXA RELPREVV therapy. Isolated cases required surgical intervention.

1 Stuttering was only studied in oral and long acting injection (LAI) formulations.

7 Drug Interactions

7.1 Potential for Other Drugs to Affect Olanzapine

Diazepam — The co-administration of diazepam with olanzapine potentiated the orthostatic hypotension observed with olanzapine [see Drug Interactions (7.2)].

CYP2D6 Inducers of CYP1A2 — Inducers of CYP1A2 may cause an approximately 50% increase in the clearance of olanzapine. This increase is likely due to the fact that carbamazepine is a potent inducer of CYP1A2 activity. Higher daily doses of carbamazepine may cause an even greater increase in olanzapine clearance.

Alcohol — Ethanol (45 mg/70 kg single dose) did not have an effect on olanzapine pharmacokinetics. The co-administration of ethanol (i.e., ethanol with olanzapine) potentiated the orthostatic hypotension observed with olanzapine [see Drug Interactions (7.2)].

Inhibitors of CYP1A2 — Fluvoxamine, a CYP1A2 inhibitor, decreases the clearance of olanzapine. This results in a mean increase in olanzapine Cmax following fluvoxamine of 54% in female nonsmokers and 77% in male smokers. The mean increase in olanzapine AUC is 52% and 108%, respectively. Lower doses of olanzapine should be considered in patients receiving concomitant treatment with fluvoxamine.

Inhibitors of CYP2D6 — Fluoxetine caused a small decrease in olanzapine clearance leading to a minimal change in olanzapine steady-state concentrations and, therefore dose modification is not routinely required.

Warfarin —Warfarin (20 mg single dose) did not affect olanzapine pharmacokinetics [see Drug Interactions (7.2)].

CYP2D6 Inducers of CYP1A2 or Glicencortone Transferase Enzymes — Omeprazole and rilmenpina may cause an increase in olanzapine clearance.

7.2 Potential for Olanzapine to Affect Other Drugs

CNS Acting Drugs — Given the primary CNS effects of olanzapine, caution should be used when olanzapine is taken in combination with other centrally acting drugs and alcohol.

Antihypertensive Agents — Olanzapine, because of its potential for inducing hypotension, may enhance the effects of certain antihypertensive agents.

Lidocaine and Dopamine Agonists — Olanzapine may antagonize the effects of levodopa and dopamine agonists.

Lorazepam (Mid) — Co-administration of lorazepam does not significantly affect the pharmacokinetics of olanzapine, unconjugated lorazepam, or total lorazepam. However, this co-administration of lorazepam with olanzapine potentiated the somnolence observed with either drug given alone.

Warfarin —Warfarin (20 mg single dose) did not affect the pharmacokinetics of olanzapine [see Drug Interactions (7.2)].

Lithium — Multiple doses of olanzapine (10 mg for 8 days) did not influence the kinetics of lithium. Therefore, concomitant olanzapine administration does not require dosage adjustment of lithium.

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Reference
8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects, Pregnancy Category C — In oral reproduction studies in rats at doses up to 18 mg/kg/day and in rabbits at doses up to 30 mg/kg/day (9 and 30 times the maximum recommended human daily oral dose on a mg/m² basis, respectively), no evidence of teratogenicity was observed. In an oral rat teratology study, early resorptions and increased numbers of nonviable fetuses were observed at a dose of 18 mg/kg/day (9 times the maximum recommended human daily oral dose on a mg/m² basis). Gestation was prolonged at 10 mg/kg/day (5 times the maximum recommended human daily oral dose on a mg/m² basis). In an oral rabbit teratology study, fetal toxicity (manifested as increased resorptions and decreased fetal weight) occurred at a maternally toxic dose of 30 mg/kg/day (30 times the maximum recommended human daily oral dose on a mg/m² basis). No evidence of teratogenicity or embryo-fetal toxicity was observed in rats or rabbits with ZYPREXA RELPREVV. Replacment of rats with ZYPREXA RELPREVV, including 1 resulting in a normal birth and 3 therapeutic abortions. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects — Neonates exposed to antipsychotic drugs (including olanzapine), during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required intensive care unit support and prolonged hospitalization.

ZYPREXA RELPREVV should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.2 Labor and Delivery

The effect of olanzapine on labor and delivery in humans is unknown. Parturition in rats was not affected by olanzapine.

8.3 Nursing Mothers

In an oral olanzapine study in lactating, healthy women, olanzapine was excreted in breast milk. Mean infant dose at steady state was estimated to be 1.9% of the maternal olanzapine dose. It is recommended that women receiving ZYPREXA RELPREVV should not breast-feed.

8.4 Pediatric Use

Safety and effectiveness of ZYPREXA RELPREVV in children and adolescent patients have not been established (see Warnings and Precautions (5.7)). Compared to patients from adult clinical trials, adolescent patients treated with oral ZYPREXA were likely to have a greater weight increase, and older patients had a lower rate of discontinuation due to adverse events than adults. Therefore, dosage recommendations for children and adolescents are not always predictive of human response. In case of acute overdose, establish and maintain an airway and ensure adequate oxygenation and ventilation, which may include intubation. The possibility of obtundation, seizures, or dystonic reaction of the head and neck following overdose may create a risk of aspiration with induced emesis. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias.

12 DESCRIPTION

ZYPREXA RELPREVV is an atypical antipsychotic that belongs to the thienobenzodiazepine class. The chemical designation is 10H-thieno[2,3-b][1,5]benzodiazepine, 2-methyl-4-[(4-methyl-1-piperazinyl)-4,4-dimethylamino]-3-hydroxy-2-naphthalene carbonylate (1:1), monohydrate. The formula is C₈H₁₁N₅S+CH₃O-H₂O, which corresponds to a molecular weight of 718.6. The chemical structure is:

ZYPREXA RELPREVV is a long-acting form of olanzapine and is intended for deep intramuscular injection only. ZYPREXA RELPREVV includes a vial of the drug product and a vial of the sterile diluent for ZYPREXA RELPREVV.

The drug product is olanzapine pamoate monohydrate, present as a yellow solid in a glass vial equivalent to 210, 300, or 405 mg olanzapine base per vial. The diluent for ZYPREXA RELPREVV is a clear, colorless to slightly yellow solution in a glass vial and is composed of carboxymethylcellulose sodium, mannitol, polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, and water for injection. The drug product is suspended in the diluent for ZYPREXA RELPREVV to a target concentration of 150 mg olanzapine per mL, prior to intramuscular injection.

13 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of olanzapine, as with other drugs having efficacy in schizophrenia, is unknown. However, it has been proposed that this drug’s efficacy in schizophrenia is mediated through a combination of dopamine and serotonin type 2 (5HT₂) antagonism.

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12.2 Pharmacodynamics

Olanzapine binds with high affinity to the following receptors: serotonin 5HT2A, 5HT3 (K_i=57 nM), dopamine D1, D2, D3, D4, D5 (K_i=11-31 nM), histamine H3 (K_i=7 nM), and adrenergic α1, α2, and β-adrenergic receptors (K_i>10 μM). Antagonism at receptors other than dopamine and 5HT7 may explain some of the other therapeutic and side effects of olanzapine. Olanzapine’s antagonism of muscarinic M1 receptors explains some of its extrapyramidal side effects. Several of these antagonistic effects may explain the somnolence observed with this drug. Olanzapine’s antagonism of adrenergic α receptors may explain the orthostatic hypotension observed with this drug.

12.3 Pharmacokinetics

The terminal pharmacokinetic properties of olanzapine are similar for ZYPREXA RELPREVV and orally administered olanzapine. Refer to the section below describing the pharmacokinetics of orally administered olanzapine for details.

Slow dissolution of ZYPREXA RELPREVV, a practically insoluble salt, after a deep intramuscular gluteal injection of a dose of ZYPREXA RELPREVV results in prolonged systemic olanzapine concentrations that are similar to those achieved by daily doses of oral olanzapine. The steady-state plasma concentrations for ZYPREXA RELPREVV for doses of 150 mg to 405 mg every 2 or 4 weeks are within the range of steady-state olanzapine plasma concentration known to have been associated with oral doses of 5 mg to 20 mg olanzapine once daily. The change to a slow release, rate-controlled absorption process is the only fundamental pharmacokinetic difference between the administration of ZYPREXA RELPREVV and orally administered olanzapine. The effective half-life for olanzapine after intramuscular ZYPREXA RELPREVV administration is approximately 30 days as compared to the half-life after orally administered 30 hours. Olanzapine may persist for a period of months after a ZYPREXA RELPREVV injection. The long persistence of systemic concentrations of olanzapine may be an important consideration for the long-term clinical management of the patient. Typical systemic olanzapine plasma concentrations peak about 1 hour and 4 hours after the first weekly injection and are at trough levels immediately prior to the next injection. The olanzapine plasma concentration fluctuation between the peak and trough is comparable to the peak and trough fluctuations associated with once daily oral dosing.

Dose Proportionality and Oral Dose Correspondence — ZYPREXA RELPREVV provides a dose of 150, 210, 300, or 405 mg olanzapine. An injection of a larger dose produces a dose-proportional increase in the systemic exposure. The olanzapine exposure after doses of ZYPREXA RELPREVV corresponds to exposure for oral doses of olanzapine. A ZYPREXA RELPREVV dose of 300 mg olanzapine injected every two weeks delivers approximately 20 mg per day and a ZYPREXA RELPREVV dose of 150 mg may be lower by two weeks delivering approximately 10 mg per day. These ZYPREXA RELPREVV doses sustain steady-state plasma concentrations over long periods of treatment.

Pharmacokinetic Impact of Switching to ZYPREXA RELPREVV from Oral Olanzapine — The switch to oral olanzapine following administration of ZYPREXA RELPREVV changes the pharmacokinetics from an elimination-rate-controlled to an absorption-rate-controlled process. The switch to ZYPREXA RELPREVV may require treatment for a period of approximately 3 months to re-establish steady-state conditions. Initial treatment with ZYPREXA RELPREVV is recommended at a dose corresponding to the mg/day oral dose [see Dosage and Administration (2.1)]. Plasma concentrations of olanzapine during the first injection interval may be lower than those maintained by a corresponding oral dose. Even though the concentrations are lower, the olanzapine concentrations remained within a therapeutically effective range and supplementation with orally administered olanzapine was generally not necessary in clinical trials.

Olanzapine is extensively metabolized. Approximately 57% and 30% of the dose was recovered in feces and urine, respectively. Olanzapine is highly metabolized. About 5% of the dose is recovered in blood. Olanzapine is glucuronide conjugate, present at steady state at 44% of the concentration of olanzapine. 4-N-desmethyl olanzapine, present at steady state at 31% of the concentration of olanzapine. Both metabolites lack pharmacological activity at the concentrations observed.

direct glucuronidation and cytochrome P450 (CYP) mediated oxidation are the primary metabolic pathways for olanzapine. In vitro studies suggest that CYPs 1A2 and 2D6, and the flavin-containing monooxygenase system are involved in olanzapine oxidation. CYP2D6 mediated oxidation appears to be a minor metabolic pathway in vivo, because the clearance of olanzapine is not reduced in patients who have never taken olanzapine. Olanzapine is metabolized by the liver and is removed by the kidneys. About 7% of the dose is recovered in urine and 5% in the feces. Olanzapine is highly metabolized. Approximately 57% and 30% of the dose was recovered in urine and feces, respectively. In the plasma, olanzapine accounted for only 12% of the AUC for total radioactivity, indicating significant exposure to metabolites. After multiple dosing, the major circulating metabolites were the 10-N-glucuronide, present at steady state at 44% of the concentration of olanzapine, and 4-N-desmethyl olanzapine, present at steady state at 31% of the concentration of olanzapine. Both metabolites lack pharmacological activity at the concentrations observed.

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13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis — Oral carcinogenicity studies were conducted in mice and rats. Olanzapine was administered to mice in two 78-week studies at doses of 3, 10, 30/20 mg/kg/day (5 times the maximum recommended human oral daily dose on a mg/m2 basis) and 100/80 mg/kg/day (2.5 times the maximum recommended human daily oral dose on a mg/m2 basis). Rats were dosed for 2 years at doses of 0.25, 1.25, 5 mg/kg/day (males) and 0.25, 1.25, 4 mg/kg/day (females) (equivalent to 0.13-2 and 0.13-4 times the maximum recommended human daily oral dose on a mg/m2 basis, respectively). The incidence of liver hemangioendotheliomas and hemangiosarcomas was significantly increased in 1 mouse study in female mice dosed at 8 mg/kg/day (2 times the maximum recommended human oral dose on a mg/m2 basis). These tumors were not increased in another mouse study in females dosed at 10 or 30/20 mg/kg/day (2.5 times the maximum recommended human daily oral dose on a mg/m2 basis); in this study, there was a high incidence of early mortalities in males of the 30/20 mg/kg/day group. The incidence of mammary gland adenomas and adenocarcinomas was significantly increased in female mice dosed at ≥2 mg/kg/day and in female rats dosed at >4 mg/kg/day (0.5 and 2 times the maximum recommended human daily oral dose on a mg/m2 basis, respectively). Rats were also dosed with ZYPREXA RELPREVV once a month for 52 weeks at doses of 5, 10, 20 mg/kg (males) and 10, 25, 50 mg/kg (females) (equivalent to 0.08-0.8 times the maximum recommended human dose of 300 mg every 2 weeks on a mg/kg basis; dosing was limited due to local reactions at the IM injection site). The incidence of tumors in this study was not altered when compared to control. Considerations for ZYPREXA RELPREVV treatment in pregnancy or lactation: Antipsychotic drugs have been shown to chronically elevate prolactin levels in rodents. Prolactin serum levels were not measured during the olanzapine carcinogenicity studies; however, measurements during subchronic toxicity studies showed that olanzapine elevated serum prolactin levels up to 4-fold in rats at the same doses used in the carcinogenicity study. An increase in mammary gland neoplasms has been found in rodents after chronic administration of other antipsychotic drugs and is considered to be prolactin mediated. The relevance for human risk of the finding of prolactin mediated endocrine tumors in rodents is unknown [see Warnings and Precautions (5.7)].

Mutagenesis — No evidence of genotoxic potential for olanzapine was found in the Ames reverse mutation test, in vivo micronucleus test in mice, the chromosomal aberration test in Chinese hamster ovary cells, unscheduled DNA synthesis test in rat hepatocytes, induction of forward mutation test in mouse lymphoma cells, or in vivo sister chromatid exchange test in bone marrow of Chinese hamsters.

Impairment of Fertility — ZYPREXA RELPREVV treatment in rats and female fertility was decreased at a dose of 3 mg/kg/day (1.5 times the maximum recommended human daily oral dose on a mg/m2 basis); therefore olanzapine may produce a delay in ovulation. Animal Toxicology and/orPharmacology

In animal studies with olanzapine, the principal hematologic findings were reversible depression of lymphocytes, neutrophils and eosinophils. In male Sprague-Dawley rats, the observed adverse effect was an increase in bone marrow of Chinese hamsters.

In male and female fertility studies in rats, ZYPREXA RELPREVV treatment was associated with an increase in fetal body weight. In female rats, this treatment reversed the effects of male mating and related to the increased incidence of hemangioendotheliomas and hemangiosarcomas in male rats. In female rats, treatment resulted in a delay in the preovulatory period and increased the mating index. In male rats, the preovulatory period was increased and the mating index reduced at 5 mg/kg/day (2.5 times the maximum recommended human daily oral dose on a mg/m2 basis). Diestrous was prolonged and estrus delayed at 1.1 mg/kg/day (0.6 times the maximum recommended human daily oral dose on a mg/m2 basis); therefore, ZYPREXA RELPREVV treatment may produce a delay in ovulation.

Animal Toxicology and/orPharmacology

In animal studies with olanzapine, the principal hematologic findings were reversible peripheral cytopenias in individual dogs dosed at 10 mg/kg (17 times the maximum recommended human daily oral dose on a mg/m2 basis), dose-related decreases in lymphocytes and neutrophils in mice, and lymphopenia in rats. A few dogs treated
10 mg/kg developed reversible neutropenia and/or reversible hemolytic anemia between 1 and 10 months of treatment. Dose-related decreases in lymphocytes and neutrophils were seen in mice given doses of 10 mg/kg (equal to 2 times the maximum recommended human daily oral dose on a mg/m² basis) in 3 of 3 months’ duration. Non-specific lymphopenia, consistent with a decreased blood weight gain, occurred in rats receiving 22.5 mg/kg (11 times the maximum recommended human daily oral dose on a mg/m² basis) for 3 months or 16 mg/kg (8 times the maximum recommended human daily oral dose on a mg/m² basis) for 6 or 12 months. No evidence of bone marrow cytotoxicity was found in any of the species studied and circulating blood cells were probably due to peripheral (non-marrow) factors.

14 CLINICAL STUDIES

14.1 Schizophrenia

The short-term effectiveness of ZYPREXA Relprevir was established in an 8-week, placebo-controlled trial in adult patients (n=404) who were experiencing psychotic symptoms and met Diagnostic and Statistical Manual of Mental Disorders, 4th edition criteria for schizophrenia. Patients were randomized to receive injections of ZYPREXA Relprevir 210 mg every 2 weeks, ZYPREXA Relprevir 405 mg every 4 weeks, ZYPREXA Relprevir 300 mg every 2 weeks, or placebo every 2 weeks. Patients were discontinued from their previous antipsychotics and underwent a 2-7 day washout period. No oral antipsychotic supplementation was allowed throughout the trial. The primary efficacy measure was change from baseline to endpoint in total Positive and Negative Syndrome Scale (PANSS) score (mean baseline total PANSS score 101). Total PANSS scores showed statistically significant improvement from baseline to endpoint with each dose of ZYPREXA Relprevir (210 mg every 2 weeks, 405 mg every 4 weeks, and 200 mg every 2 weeks) as compared to placebo. The effectiveness of ZYPREXA Relprevir in the treatment of schizophrenia is further supported by the established effectiveness of the oral formulation of olanzapine.

A 2-year, long-term enrollee patients with schizophrenia (n=1005) who had remained stable for 4 to 8 weeks on open-label treatment with oral olanzapine (mean baseline total PANSS score 65) and were then randomized to continue their current oral olanzapine dose (10, 15, or 20 mg/day); or to ZYPREXA Relprevir 150 mg every 2 weeks (0.5 mg every 4 weeks, 0.6 mg every 4 weeks, or 0.45 mg every 4 weeks). No oral antipsychotic supplementation was allowed throughout the trial. The clinical efficacy measure was time to exacerbation of symptoms of schizophrenia defined in terms of increases in Brief Psychiatric Rating Scale (BPRS) positive symptoms or hospitalization. ZYPREXA Relprevir doses of 150 mg every 2 weeks, 405 mg every 4 weeks, and 400 mg every 2 weeks were each statistically significantly superior to low dose ZYPREXA Relprevir (45 mg every 4 weeks).

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

ZYPREXA Relprevir convenience kit is supplied in single-use cartons. Each carton includes one vial of olanzapine pamoate monohydrate in dosage strengths that are equivalent to 210 mg olanzapine (420 mg olanzapine pamoate monohydrate), 300 mg olanzapine (600 mg olanzapine pamoate monohydrate), and 450 mg olanzapine (900 mg olanzapine pamoate monohydrate) per vial; one vial of approximately 3 mL of diluent for ZYPREXA Relprevir used to suspend the drug product; one 3 mL syringe with pre-attached 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needle with needle protection device, and one 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needles with needle protection device. Needle-Pro® is a registered trademark of Smiths Medical.

NDC 002-7635-11 — single-use convenience kit: 210 mg vial (VL7635) with 3 mL of sterile diluent (VL7622) with gray flip-off cap and 3 mL of sterile diluent (VL7623) with steel blue flip-off cap and 450 mg vial (VL7635) with 3 mL of sterile diluent (VL7622) with gray flip-off cap and 3 mL of sterile diluent (VL7623) with steel blue flip-off cap and 3 mL of sterile diluent (VL7622) with gray flip-off cap.

16.2 Storage and Handling

ZYPREXA Relprevir should be stored at room temperature not to exceed 85°F (30°C). When the drug product is suspended in the solution for ZYPREXA Relprevir, it may be held at room temperature for 24 hours. The vial should be agitated immediately prior to product withdrawal. Once the suspension is withdrawn into the syringe, it should be used immediately [see Dosage and Administration (2.1) and Warnings and Precautions (5.1, 5.1.4)].

17 PATIENT COUNSELING INFORMATION

See FDA-approved Medication Guide

Patients should be advised of the following issues and asked to alert their prescriber if these occur while taking ZYPREXA Relprevir. Patients should be advised to call their doctor if they do not think they are getting better or have concerns about their condition.

17.1 Information on Medication Guide

Prescribers or other health professionals should inform patients, their families, and their caregivers about the potential benefits and potential risks associated with treatment with ZYPREXA Relprevir, and should counsel them in its appropriate use. A patient Medication Guide is available for ZYPREXA Relprevir. Prescribers or other health professionals should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have.

17.2 Post-Injection Delirium/Sedation Syndrome

Diagnosis of postmarketing clinical studies, reactions that presented with signs and symptoms consistent with olanzapine overdose have been reported in patients following an injection of ZYPREXA Relprevir. It is mandatory that patients be enrolled in the ZYPREXA Relprevir Patient Care Program to receive ZYPREXA Relprevir treatment. Patients should be advised of the risk of developing this syndrome when they receive an injection. [see Warnings and Precautions (5.1, 5.2)]. Patients and caregivers should be advised that after each ZYPREXA Relprevir injection, patients must be observed at the healthcare facility for at least 3 hours and must be accompanied to their destination upon leaving the facility. The Medication Guide should be distributed each time patients receive an injection.

ZYPREXA Relprevir (olanzapine)

For Extended Release Injectable Suspension

ZYPRE-0007-USP-20180119

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ZYPREXA Relprevir, ZYPRE-0007-USP-20180119_ZYPRE-0001-MG-20161006

Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, USA
Medication Guide
ZYPREXA® RELPREV™ (zy-PREX-a REL-prev)
(olanzapine)

For Extended Release Injectable Suspension

Read the Medication Guide that comes with ZYPREXA RELPREV before you start taking it and each time before you get an injection. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment. Talk with your doctor if there is something you do not understand or you want to learn more about ZYPREXA RELPREV.

What is the most important information I should know about ZYPREXA RELPREV?

Before you receive ZYPREXA RELPREV treatment you must:

• understand the risks and benefits of ZYPREXA RELPREV treatment. Your doctor will talk to you about the risks and benefits of ZYPREXA RELPREV treatment.
• register in the ZYPREXA RELPREV Patient Care Program. You must agree to the rules of the ZYPREXA RELPREV Patient Care Program before you register.

ZYPREXA RELPREV may cause serious side effects, including:

1. Post-injection Delirium Sedation Syndrome (PDSS).
2. Increased risk of death in elderly people who are confused, have memory loss and have lost touch with reality (dementia-related psychosis).
3. High blood sugar (hyperglycemia).
4. High fat levels in your blood (increased cholesterol and triglycerides), especially in teenagers age 13 to 17.
5. Weight gain, especially in teenagers age 13 to 17.

These serious side effects are described below.

1. Post-injection Delirium Sedation Syndrome (PDSS). PDSS is a serious problem that can happen after you get a ZYPREXA RELPREV injection if the medicine gets in your blood too fast. This problem usually happens within 3 hours after you receive ZYPREXA RELPREV. If the medicine gets in your blood too fast, you may have some of the following symptoms:

• feel more sleepy than usual
• feel dizzy
• feel confused or disoriented
• trouble talking or walking
• muscles feel stiff or shaking
• feel weak
• feel grouchy or angry
• feel nervous or anxious
• higher blood pressure
• seizures (convulsions)
• pass out (become unconscious or coma)

You will need to stay at the clinic where you receive the injection for at least 3 hours so your doctor can make sure you do not have symptoms of PDSS. When you leave the clinic someone must be with you. If you have symptoms of PDSS after you leave the clinic, get medical help or go to an emergency room right away.

2. Increased risk of death in elderly people who are confused, have memory loss and have lost touch with reality (dementia-related psychosis). ZYPREXA RELPREV is not approved for treating psychosis in elderly people with dementia.

3. High blood sugar (hyperglycemia). High blood sugar can happen if you have diabetes already or if you have never had diabetes. High blood sugar could lead to:

• a build up of acid in your body due to ketones (ketoacidosis)
• coma
• death

Your doctor should do tests to check your blood sugar before you start taking ZYPREXA RELPREV and during treatment. In people who do not have diabetes, sometimes high blood sugar goes away when ZYPREXA RELPREV is stopped. People with diabetes and some people who did not have diabetes before taking ZYPREXA RELPREV need to take medicine for high blood sugar even after they stop taking ZYPREXA RELPREV.

If you have diabetes, follow your doctor’s instructions about how often to check your blood sugar while taking ZYPREXA RELPREV.

Call your doctor if you have any of these symptoms of high blood sugar (hyperglycemia) while taking ZYPREXA RELPREV:

• feel very thirsty
• need to urinate more than usual
• feel very hungry
• feel weak or tired
• feel sick to your stomach
• feel confused or your breath smells fruity

4. High fat levels in your blood (cholesterol and triglycerides). High fat levels may happen in people treated with ZYPREXA RELPREV, especially in teenagers (13 to 17 years old). ZYPREXA RELPREV is not approved in patients less than 18 years old. You may not have any symptoms, so your doctor should do blood tests to check your cholesterol and triglyceride levels before you start taking ZYPREXA RELPREV and during treatment.

5. Weight gain. Weight gain is very common in people who take ZYPREXA RELPREV. Teenagers (13 to 17 years old) are more likely to gain weight and to gain more weight than adults. ZYPREXA RELPREV is not approved in patients less than 18 years old. Some people may gain a lot of weight while taking ZYPREXA RELPREV, so you and your doctor should check your weight regularly. Talk to your doctor about ways to control weight gain, such as eating a healthy, balanced diet, and exercising.

What is ZYPREXA RELPREV?

ZYPREXA RELPREV is a long-acting prescription medicine given by injection and used to treat schizophrenia in adults. The symptoms of schizophrenia include:

• hearing voices
• seeing things that are not there
• having beliefs that are not true
• being suspicious or withdrawn

Some of your symptoms of schizophrenia may improve with treatment with ZYPREXA RELPREV. If you do not think you are getting better, call your doctor.

It is not known if ZYPREXA RELPREV is safe and effective in children under 18 years of age.

What should I tell my doctor before taking ZYPREXA RELPREV?

ZYPREXA RELPREV may not be right for you. Before starting ZYPREXA RELPREV, tell your doctor if you have or had:

• heart problems
• seizures
• diabetes or high blood sugar levels (hyperglycemia)
high cholesterol or triglyceride levels in your blood
- liver problems
- low or high blood pressure
- strokes or “mini-strokes” also called transient ischemic attacks (TIAs)
- Alzheimer's disease
- narrow-angle glaucoma
- enlarged prostate in men
- bowel obstruction
- breast cancer
- thoughts of suicide or hurting yourself
- any other medical condition
- are pregnant or plan to become pregnant. It is not known if ZYPREXA RELPREV will harm your unborn baby.
- are breastfeeding or plan to breast-feed. ZYPREXA RELPREV can pass into your breast milk and may harm your baby. You should not breast-feed while taking ZYPREXA RELPREV. Talk to your doctor about the best way to feed your baby if you take ZYPREXA RELPREV.

Tell your doctor if you exercise a lot or are in hot places often.

The symptoms of schizophrenia may include thoughts of suicide or of hurting yourself or others. If you have these thoughts at any time, tell your doctor or go to an emergency room right away.

Tell your doctor about all the medicines that you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. ZYPREXA RELPREV and some medicines may interact with each other and may not work as well, or cause possible serious side effects. Your doctor can tell you if it is safe to take ZYPREXA RELPREV with your other medicines. Do not start or stop any medicine while taking ZYPREXA RELPREV without talking to your doctor first.

How should I receive ZYPREXA RELPREV?

- ZYPREXA RELPREV will be injected into the muscle in your buttock (gluteus) by your doctor or nurse at the clinic.
- After receiving ZYPREXA RELPREV, you will need to stay at the clinic for at least 3 hours.
- When you leave the clinic, someone must be with you.
- Call your doctor if you do not think you are getting better or have any concerns about your condition while taking ZYPREXA RELPREV.

What should I avoid while receiving ZYPREXA RELPREV?

- ZYPREXA RELPREV can cause sleepiness and may affect your ability to make decisions, think clearly, or react quickly. Do not drive, operate heavy machinery, or do other dangerous activities until you know how ZYPREXA RELPREV affects you. You should not drive or operate heavy machinery for the rest of the day after each injection.
- Avoid drinking alcohol while taking ZYPREXA RELPREV. Drinking alcohol while you take ZYPREXA RELPREV may make you sleepy than if you take ZYPREXA RELPREV alone.

What are the possible side effects of ZYPREXA RELPREV?

Serious side effects may happen when you take ZYPREXA RELPREV, including:

- See “What is the most important information I should know about ZYPREXA RELPREV?”, which describes the risk of post-injection delirium sedation syndrome (PDSS), increased risk of death in elderly people with dementia-related psychosis and the risks of high blood sugar, high cholesterol and triglyceride levels, and weight gain.
- Increased incidence of stroke or “mini-strokes” called transient ischemic attacks (TIAs) in elderly people with dementia-related psychosis (elderly people who have lost touch with reality due to confusion and memory loss). ZYPREXA RELPREV is not approved for these patients.
- Neuroleptic Malignant Syndrome (NMS): NMS is a rare but very serious condition that can happen in people who take antipsychotic medicines, including ZYPREXA RELPREV. NMS can cause death and must be treated in a hospital. Call your doctor right away if you become severely ill and have any of these symptoms:
  - high fever
  - excessive sweating
  - rigid muscles
  - confusion
  - changes in your breathing, heartbeat, and blood pressure
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): DRESS can occur with ZYPREXA RELPREV. Features of DRESS may include rash, fever, swollen glands and other internal organ involvement such as liver, kidney, lung and heart. DRESS is sometimes fatal; therefore, tell your doctor immediately if you experience any of these signs.
- Tardive Dyskinesia: This condition causes body movements that keep happening and that you can not control. These movements usually affect the face and tongue. Tardive dyskinesia may not go away, even if you stop taking ZYPREXA RELPREV. It may also start after you stop taking ZYPREXA RELPREV. Tell your doctor if you get any body movements that you can not control.
- Decreased blood pressure when you change positions, with symptoms of dizziness, fast or slow heartbeat, or fainting.
- Difficulty swallowing, that can cause food or liquid to get into your lungs.
- Seizures: Tell your doctor if you have a seizure during treatment with ZYPREXA RELPREV.
- Problems with control of body temperature: You could become very hot, for instance when you exercise a lot or stay in an area that is very hot. It is important for you to drink water to avoid dehydration. Call your doctor right away if you become severely ill and have any of these symptoms of dehydration:
  - sweating too much or not at all
  - dry mouth
  - feeling very hot
  - feeling thirsty
  - not able to produce urine

Common side effects of ZYPREXA RELPREV include: headache, sleepiness or drowsiness, weight gain, dry mouth, diarrhea, nausea, common cold, eating more (increased appetite), vomiting, cough, back pain, or pain at the injection site.

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the possible side effects with ZYPREXA RELPREV. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
General information about ZYPREXA RELPREVX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about ZYPREXA RELPREVX. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ZYPREXA RELPREVX that was written for healthcare professionals. For more information about ZYPREXA RELPREVX call 1-800-Lilly-Rx (1-800-545-5979) or visit www.zyrexarelpревx.com.

What are the ingredients in ZYPREXA RELPREVX?

Active ingredient: olanzapine

Inactive ingredients: carboxymethylcellulose sodium, mannitol, polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, and water for injection

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide revised October 6, 2016

Marketed by: Lilly USA, LLC
Indianapolis, IN 46285, USA
www.zyrexarelpревx.com

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ZYPREX-0001-MG-20161006
ZYPREXA RELPREVX (olanzapine)
For Extended Release Injectable Suspension ZYPREX-0001-MG-20161006
To be enrolled in the ZYPREXA RELPREVV Patient Care Program, complete and fax this form to 1-877-772-9391.

Training must be completed before a prescriber may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

**PRESCRIBER INFORMATION**

☐ Enrollment  ☐ Reenrollment

First Name: ___________________________ MI: _______ Last Name: ___________________________

Degree:  ☐ MD  ☐ DO  ☐ NP  ☐ PA  ☐ Nurse with prescriptive authority  ☐ Other with prescriptive authority

License Number: ___________________________ State of Issue: ___________________________

Treatment Facility/Practice (Where you see your patients):

*If you see your patients at multiple locations please contact the ZYPREXA RELPREVV Patient Care Program Coordinating Center to provide additional facility/practice information*

Address Line 1: ___________________________

Address Line 2: ___________________________

City: ___________________________ State: _____________ Zip: ___________________________

Phone: ___________________________ Alternate Phone: ___________________________

Fax: ___________________________ Prescriber Email: ___________________________

Preferred Method of Communication:  ☐ Email  ☐ Fax

**PRESCRIBER AGREEMENT**

By signing below, I acknowledge that:

- I understand the ZYPREXA RELPREVV Patient Care Program requirements and the risks associated with ZYPREXA RELPREVV.
- I have completed the mandatory ZYPREXA RELPREVV training.
- I understand the clinical presentation of post-injection delirium/sedation syndrome (PDSS) and how to manage patients should an event occur while using ZYPREXA RELPREVV.
- I understand that ZYPREXA RELPREVV should only be initiated in patients for whom tolerability with oral olanzapine has been established.
- I understand that ZYPREXA RELPREVV should only be administered to patients in healthcare settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.
- I will enroll all patients in the ZYPREXA RELPREVV Patient Care Program registry prior to prescribing ZYPREXA RELPREVV by completing the Patient Registration Form.
- I will ensure all suspected cases of PDSS are reported to the ZYPREXA RELPREVV Patient Care Program within 24 hours of becoming aware of the event.
- I will review the ZYPREXA RELPREVV Medication Guide with each patient prior to prescribing.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact me to resolve discrepancies, to obtain information about a patient, or to conduct occasional surveys.

I may cancel this registration by notifying the ZYPREXA RELPREVV Patient Care Program Coordinating Center by fax at 1-877-772-9391 or by phone at 1-877-772-9390.

If I revoke my registration, I will no longer be eligible to prescribe ZYPREXA RELPREVV.

Lilly may disenroll prescribers that are non-compliant with the program requirements.

Signed: ___________________________

Date: ___________________________

month  day  year

Prescriber Signature

PHONE 1-877-772-9390  FAX 1-877-772-9391  www.zyprexarelprevvprogram.com

CONFIDENTIAL

Reference ID: 4417451
PHARMACY REGISTRATION FORM

To be enrolled in the ZYPREXA RELPREVX Patient Care Program, complete and fax this form to 1-877-772-9391.

Training must be completed before a pharmacy may be enrolled in the ZYPREXA RELPREVX Patient Care Program.

PHARMACY INFORMATION

- Enrollment
- Reenrollment

Pharmacy/Hospital Name: __________________________________________

Pharmacy DEA Number: _________________________________________

Please specify description of Pharmacy:  
- Community/Retail
- Specialty Pharmacy
- Hospital or Institution
- Other

Address Line 1: ___________________________________________________

Address Line 2: ___________________________________________________

City: __________________________ State: ______________ Zip: __________

Primary Phone: __________________________ Secondary Phone: _________

Fax: __________________________

SHIP TO INFORMATION

Ship To Address (if the same as above, check here) □

Ship To Contact Name: ________________________________

Address Line 1: __________________________________________

Address Line 2: __________________________________________

City: __________________________ State: ______________ Zip: __________

Primary Phone: __________________________ Secondary Phone: _________

Fax: __________________________

PHARMACIST-IN-CHARGE INFORMATION

First Name: __________________________ M: ______ Last Name: ____________

Email: ______________________________

Phone: __________________________ Fax: __________________________

(if different from above) (if different from above)

PHARMACIST-IN-CHARGE INFORMATION

By signing below, I acknowledge that:

- I have read and understand the ZYPREXA RELPREVX Patient Care Program Instructions Brochure.
- I will ensure that all appropriate pharmacy staff are trained and have read and understand the ZYPREXA RELPREVX Patient Care Program Instructions Brochure.
- I will ensure that all appropriate pharmacy staff understand that ZYPREXA RELPREVX can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.
- I will ensure that pharmacy staff will verify that the patient is enrolled in the ZYPREXA RELPREVX Patient Care Program registry prior to dispensing each prescription/refill by accessing the system.
- I will ensure that pharmacy staff will not dispense ZYPREXA RELPREVX directly to patients.
- I will ensure pharmacy staff report the date of each ZYPREXA RELPREVX dispensing to the ZYPREXA RELPREVX Patient Care Program.
- For each dispense, I will ensure prescription verification (includes patient eligibility check and recording the dispense date) is completed on the date of dispense, prior to the visit kit leaving the pharmacy.
- I understand that the ZYPREXA RELPREVX Patient Care Program Coordinating Center may contact the pharmacy to clarify information provided or obtain information about the patient.

I may cancel this registration by notifying the ZYPREXA RELPREVX Patient Care Program Coordinating Center by fax at 1-877-772-9390 or by phone at 1-877-772-9390. If I cancel, Lilly will cease to supply ZYPREXAreLRELPREVX to the pharmacy.

Pharmacist-in-Charge Signature

Date: □ □ □ □

PHONE 1-877-772-9390  FAX 1-877-772-9391  www.zypraxarelprevxprogram.com

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Reference ID: 4188742  Reference ID: 417451
HEALTHCARE FACILITY REGISTRATION FORM

To be enrolled in the ZYPREXA RELPREV V Patient Care Program, complete and fax this form to 1-877-772-9391.
Training must be completed before a healthcare facility may be enrolled in the ZYPREXA RELPREV V Patient Care Program.

HEALTHCARE FACILITY INFORMATION

- Enrollment
- Reenrollment

Healthcare Facility Name: ____________________________

Please specify location of Healthcare Facilities: ☐ Prescriber Office ☐ Clinic/Outpatient Facility ☐ Hospital ☐ Other

Address: ____________________________

City: ____________________________ State: ____________ Zip: ____________

Phone: ____________________________ Fax: ____________________________

AUTHORIZED HEALTHCARE FACILITY REPRESENTATIVE INFORMATION

First Name: ____________________________ MI: _____ Last Name: ____________________________

Position/Title: ____________________________

Phone: ____________________________ Fax: ____________________________

Email: ____________________________

Preferred Method of Communication: ☐ Email ☐ Fax

You may identify Delegate(s) to enter the necessary patient data into the Patient Care Program system.

Delegate First Name: ____________________________ MI: _____ Last Name: ____________________________

Facility Name: ____________________________

Phone: ____________________________ Fax: ____________________________

Email: ____________________________

Delegate First Name: ____________________________ MI: _____ Last Name: ____________________________

Facility Name: ____________________________

Phone: ____________________________ Fax: ____________________________

Email: ____________________________

Delegate First Name: ____________________________ MI: _____ Last Name: ____________________________

Facility Name: ____________________________

Phone: ____________________________ Fax: ____________________________

Email: ____________________________

Delegate First Name: ____________________________ MI: _____ Last Name: ____________________________

Facility Name: ____________________________

Phone: ____________________________ Fax: ____________________________

Email: ____________________________

If additional Delegates are required contact the Patient Care Program Coordinating Center.

PHONE 1-877-772-9390 FAX 1-877-772-9391 www.zyprexarelprevprogram.com

Version 2.0 03Aug2012 CONFIDENTIAL
HEALTHCARE FACILITY AGREEMENT

As the authorized representative for this facility, I attest that:

- I have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure;

- I will ensure that all appropriate staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure as well as the following Training Materials:
  - ZYPREXA RELPREVV Healthcare Professional Training
  - ZYPREXA RELPREVV Reconstitution and Administration Training

- I will ensure that all appropriate staff understand that ZYPREXA RELPREVV can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection;

- I will ensure the health care setting has systems, protocols, or other measures to ensure that ZYPREXA RELPREVV is only administered to patients enrolled in the program and that patients are continuously monitored for at least 3 hours post-injection for suspected PDSS;

- I will ensure that appropriate staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to each injection, by accessing the system;

- I will ensure that the Medication Guide is provided to the patient or the patient’s legal guardian prior to each injection;

- I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours;

- I will ensure that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVV Patient Care Program.

- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the health care setting to clarify information provided or to obtain information about the patient.

I confirm that the information above is correct.

I understand that this information will be used to document healthcare facilities that are eligible to administer ZYPREXA RELPREVV.

I also understand that this information may be shared with government agencies.

I understand that Lilly will regularly evaluate ZYPREXA RELPREVV Patient Care Program compliance to ensure that program objectives are met. Lilly reserves the right to terminate a healthcare facility’s enrollment at any time based upon non-compliance or to take other appropriate measures to assure that the ZYPREXA RELPREVV Patient Care Program objectives are met.

I may cancel this healthcare facility registration in the future by notifying Lilly in writing and submitting the notification by fax to 1-877-772-9391 or by calling 1-877-772-9390. If I revoke this facility’s registration, the facility will no longer be eligible to administer ZYPREXA RELPREVV to patients.

Authorized Healthcare Facility Representative Signature

Date: ____________

month — day — year

Authorized Healthcare Facility Representative Name (print) ____________________________

Title ____________________________

Please fax completed form to the ZYPREXA RELPREVV Patient Care Program at 1-877-772-9391.

PHONE 1-877-772-9390       FAX 1-877-772-9391       www.zyprexa relieving program.com

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Reference ID: 4417451
PATIENT REGISTRATION FORM

To be enrolled in the ZYPREXA RELPREVU Patient Care Program, complete and fax this form to 1-877-772-9391.

PATIENT INFORMATION

First Name: ___________________________ MI: _____ Last Name: ___________________________

Date of Birth: ___________________________

Gender:  □ Male    □ Female

Race:  □ White    □ Black or African American    □ Native Hawaiian or Other Pacific Islander
       □ Asian    □ American Indian or Alaska Native    □ Other

Ethnicity:  □ Hispanic or Latino
           □ Non-Hispanic/Non-Latino

PRESCRIBER INFORMATION

First Name: ___________________________ MI: _____ Last Name: ___________________________

License Number: ___________________________ State of Issue: ___________________________

Treatment Facility/Practice Name (where you see the patient): ___________________________

Address Line 1: ___________________________

Address Line 2: ___________________________

Will the patient be injected/monitored at your facility/practice?

□ Yes

□ No  (If No, complete next section)

INJECTING/MONITORING FACILITY INFORMATION

Facility Name (where the patient receives injections or monitoring): ___________________________

Address Line 1: ___________________________

Address Line 2: ___________________________

City: ___________________________ State: _______ Zip: ___________________________
PATIENT AGREEMENT

The maker of ZYPREXA RELPREVV, Eli Lilly and Company and their delegates run the ZYPREXA RELPREVV Patient Care Program.

Your doctor will send your name, date of birth, and other information that directly identifies you to the ZYPREXA RELPREVV Patient Care Program. Ask your doctor if you have questions about the information that will be collected.

The ZYPREXA RELPREVV Patient Care Program will collect and use your information in the following ways:

• Your doctor will provide dose, date and time of each injection, and other medical information to the ZYPREXA RELPREVV Patient Care Program.

• Your information will be stored in the ZYPREXA RELPREVV Patient Care Program computer system.

• The information will be used to help Lilly learn more about the safety of ZYPREXA RELPREVV.

• Information from all patients in the ZYPREXA RELPREVV Patient Care Program will be reviewed and may be combined with information from clinical studies.

• This combined information will not be able to identify you or any other patient. This combined information may be shared with:
  • regulatory agencies,
  • doctors at other institutions,
  • the committee overseeing the ZYPREXA RELPREVV Patient Care Program, and/or
  • publications or as part of scientific discussions.

Also, by signing this form you agree to the following:

• I understand that I must enroll in the ZYPREXA RELPREVV Patient Care Program registry to get ZYPREXA RELPREVV.

• I agree to have my information entered in the ZYPREXA RELPREVV Patient Care Program registry.

• My doctor has explained the risks and benefits of treatment with ZYPREXA RELPREVV.

• I have received a copy of the Medication Guide.

• I understand that I will be observed at the clinic for 3 hours after each injection.

• Someone must go with me to my destination when I leave the clinic.

• I understand that I can not drive or use heavy machinery for the rest of the day on which I get an injection.

• I agree to seek medical care right away if I have a reaction such as excessive sleepiness, dizziness, confusion, difficulty talking, difficulty walking, muscle stiffness or shaking, weakness, irritability, aggression, anxiety, increase in blood pressure or convulsions.

• I agree to contact my doctor if I have a reaction to ZYPREXA RELPREVV.

• I may be asked to complete occasional surveys about my understanding of the risks and benefits of treatment with ZYPREXA RELPREVV.

• I or my caregiver have discussed any questions or concerns about my treatment with ZYPREXA RELPREVV with my doctor.

You may stop participating in the ZYPREXA RELPREVV Patient Care Program at any time by telling your doctor. If you stop participating, you will no longer be able to receive the drug. Your doctor will no longer provide any of your information to the ZYPREXA RELPREVV Patient Care Program except to answer safety questions. The ZYPREXA RELPREVV Patient Care Program will still use information that was collected before you stopped participating. You will be provided a copy of this form.

__Signature__

Date: ______________ month  ______________ day  ______________ year

Printed Name of Patient

__________

Printed Name of Legal Guardian (if applicable)

☐ Check the box if the patient has not signed due to enrollment decision being made by prescriber who is authorized via a court order.

Date of Court Order Expiration (MMDYYYY) ______________

☐ This patient has been shown to be tolerant of oral olanzapine.

__Signature of Prescriber__

Date: ______________ month  ______________ day  ______________ year

Printed Name of Prescriber

______

PHONE 1-877-772-9390  FAX 1-877-772-9391  www.zyprexa relprev program.com

Version 2.0  03Aug2012

CONFIDENTIAL

Lilly

Reference ID: 4417451
BUY & BILL* PHARMACY SERVICE PROVIDER REGISTRATION FORM

To be enrolled in the ZYPREXA Relprevv Patient Care Program, complete and fax this form to 1-877-772-9391.

Training must be completed before a pharmacy service provider may be enrolled in the ZYPREXA Relprevv Patient Care Program.

PHARMACY SERVICE PROVIDER INFORMATION

☐ Enrollment  ☐ Reenrollment

Facility Name: ____________________________

DEA Number: ____________________________

Please specify description of Pharmacy: ☐ Community/Retail  ☐ Specialty Pharmacy  ☐ Hospital or Institution  ☐ Other

Address Line 1: __________________________

Address Line 2: __________________________

City: __________________ State: __________ Zip: __________

Primary Phone: __________________ Secondary Phone: __________________

Fax: __________________

SHIP TO INFORMATION

Ship To Address (if the same as above, check here) ☐

Ship To Contact Name: __________________

Address Line 1: __________________

Address Line 2: __________________

City: __________________ State: __________ Zip: __________

Primary Phone: __________________ Secondary Phone: __________________

Fax: __________________

ADMINISTRATOR INFORMATION

First Name: ___________________ MI: ______ Last Name: ___________________

Preferred Method of Communication: ☐ Email  ☐ Fax

Email: __________________________

Phone: _______________________ Fax: __________________ (if different from above)

PHARMACY SERVICE PROVIDER AGREEMENT

By signing below, I acknowledge that:

- I have read and understand the ZYPREXA Relprevv Patient Care Program Instructions Brochure.
- I will ensure that all appropriate pharmacy staff are trained and have read and understand the ZYPREXA Relprevv Patient Care Program Instructions Brochure.
- I will ensure that all appropriate pharmacy staff understand that ZYPREXA Relprevv can only be dispensed for use in certain healthcare settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.
- I will ensure that pharmacy staff will verify that the patient is enrolled in the ZYPREXA Relprevv Patient Care Program registry prior to dispensing each prescription/refill by accessing the system.
- I will ensure that pharmacy staff will not dispense ZYPREXA Relprevv directly to patients.
- I will ensure pharmacy staff report the date of each ZYPREXA Relprevv dispensing to the ZYPREXA Relprevv Patient Care Program.
- For each dispense I will ensure prescription verification (includes patient eligibility check and recording the dispense date) is completed on the date of dispense, prior to the convenience kit leaving the pharmacy.
- I understand that the ZYPREXA Relprevv Patient Care Program Coordinating Center may contact the pharmacy to clarify information provided or to obtain information about the patient.

I may cancel this registration by notifying the ZYPREXA Relprevv Patient Care Program Coordinating Center by fax at 1-877-772-9391 or by phone at 1-877-772-9390. If I cancel, Lilly will cease to supply ZYPREXA Relprevv to the facility.

Administrator Signature ____________________________

Date: ____________ month ____________ day ____________ year ____________

* Buy & Bill Pharmacy Service Provider - a licensed healthcare provider that purchases pharmaceuticals through a licensed distributor for its own use in the treatment of a patient and then includes the cost of the pharmaceutical in its billing of patients and third-party payers.

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Version 4.0 30Dec2014

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Page 1 of 1

Lilly
Title: ZYPREXA RELPREVV Reconstitution and Administration Training Video

DVD Menu: (Note: the menu only appears on the DVD copies of this video. The digital version used on www.zyprexarelprevvprogram.com is a continuous streaming video and cannot be viewed in chapters. This is consistent with the previously approved version of this video.)
<table>
<thead>
<tr>
<th>VIDEO</th>
<th>AUDIO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Text on-screen:</strong></td>
<td><strong>Music</strong></td>
</tr>
<tr>
<td>ZYPREXA RELPREVV logo</td>
<td></td>
</tr>
<tr>
<td>ZYPREXA RELPREVV Reconstitution and Administration Training</td>
<td></td>
</tr>
<tr>
<td><strong>Text on-screen:</strong></td>
<td><strong>Music</strong></td>
</tr>
<tr>
<td>ZYPREXA RELPREVV logo</td>
<td></td>
</tr>
<tr>
<td>Chapter One: Introduction</td>
<td></td>
</tr>
<tr>
<td><strong>Text on-screen:</strong></td>
<td></td>
</tr>
<tr>
<td>ZYPREXA RELPREVV (olanzapine) For Extended</td>
<td></td>
</tr>
<tr>
<td>Release Injectable Suspension is an antipsychotic agent indicated</td>
<td></td>
</tr>
<tr>
<td>for the treatment of schizophrenia in adults.</td>
<td></td>
</tr>
<tr>
<td><strong>Text on-screen:</strong></td>
<td></td>
</tr>
<tr>
<td>All healthcare professionals who administer this product must view</td>
<td></td>
</tr>
<tr>
<td>this video before giving an injection of ZYPREXA RELPREVV.</td>
<td></td>
</tr>
<tr>
<td>For important safety Information, including boxed warnings, see the</td>
<td></td>
</tr>
<tr>
<td>full prescribing information provided.</td>
<td></td>
</tr>
<tr>
<td><strong>Visual:</strong></td>
<td></td>
</tr>
<tr>
<td>Nurse (talent) talking to camera</td>
<td></td>
</tr>
<tr>
<td>ZYPREXA RELPREVV is a long acting injectable formulation of</td>
<td></td>
</tr>
<tr>
<td>olanzapine. It is indicated for the treatment of schizophrenia in</td>
<td></td>
</tr>
<tr>
<td>adults. The efficacy of ZYPREXA RELPREVV is consistent with the</td>
<td></td>
</tr>
<tr>
<td>established efficacy of orally administered Zyprexa for treatment</td>
<td></td>
</tr>
<tr>
<td>of schizophrenia in adults.</td>
<td></td>
</tr>
<tr>
<td><strong>Text on-screen:</strong></td>
<td></td>
</tr>
<tr>
<td>Vial Strengths:</td>
<td></td>
</tr>
<tr>
<td>• 210-mg, 300-mg, and 405-mg</td>
<td></td>
</tr>
<tr>
<td>Dosing Schedules:</td>
<td></td>
</tr>
<tr>
<td>• Every 2 weeks: 150-mg, 210-mg, or 300-mg</td>
<td></td>
</tr>
<tr>
<td>• Every 4 weeks: 300-mg or 405-mg</td>
<td></td>
</tr>
<tr>
<td><strong>Visual:</strong></td>
<td></td>
</tr>
<tr>
<td>Nurse talking to camera</td>
<td></td>
</tr>
<tr>
<td>ZYPREXA RELPREVV is available in 210-, 300-, and 405-</td>
<td></td>
</tr>
<tr>
<td>milligram vials. It may be administered every 2 weeks in 150-mg,</td>
<td></td>
</tr>
<tr>
<td>210-mg, or 300-mg doses, or every 4 weeks in 300-mg or 405-mg doses.</td>
<td></td>
</tr>
<tr>
<td><strong>Text on-screen:</strong></td>
<td></td>
</tr>
<tr>
<td>First we will begin by explaining the Post-Injection Delirium/Sedation</td>
<td></td>
</tr>
<tr>
<td>Syndrome events that occurred with ZYPREXA RELPREVV in pre-marketing</td>
<td></td>
</tr>
<tr>
<td>clinical trials.</td>
<td></td>
</tr>
<tr>
<td>Then, we will demonstrate step-by-step instructions on how to</td>
<td></td>
</tr>
<tr>
<td>properly reconstitute the product.</td>
<td></td>
</tr>
<tr>
<td>Once it has been reconstituted, we will show you the proper</td>
<td></td>
</tr>
<tr>
<td>administration techniques and demonstrate the entire reconstitution</td>
<td></td>
</tr>
<tr>
<td>and administration process in real time.</td>
<td></td>
</tr>
</tbody>
</table>

Reference ID: 4417451
Post-Injection Delirium/Sedation Syndrome

Text on screen: ZYPREXA RELPREVV logo

Chapter Two: Post-Injection Delirium/Sedation Syndrome

Visual: Nurse talking to camera

During pre-marketing clinical studies, events that presented with signs and symptoms consistent with olanzapine overdose were reported in some patients following an injection of ZYPREXA RELPREVV.

Text on screen: Events occurred:
- in < 0.1% of injections
- in approximately 2% of patients

These events occurred in <0.1% of injections and in approximately 2% of patients who received injections for up to 46 months.

Text on screen: Symptoms:
- Sedation: ranging from mild in severity up to coma
- Delirium: confusion, disorientation, agitation, anxiety, other cognitive impairment
- Other Symptoms: extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension, possible convulsion

Most of these patients developed symptoms of sedation, ranging from mild in severity up to coma, and/or delirium, including confusion, disorientation, agitation, anxiety and other cognitive impairment. Other symptoms noted included extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension or possible convulsion.

Text on screen: PDSS Symptom Onset:

<table>
<thead>
<tr>
<th>Time of Onset of Symptoms</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;60 min</td>
<td>~ 80%</td>
</tr>
<tr>
<td>1 to 3 hours</td>
<td>~ 14%</td>
</tr>
<tr>
<td>&gt;3 hours</td>
<td>~ 6%</td>
</tr>
</tbody>
</table>

In pre-marketing clinical trials, the potential for onset of a PDSS event was greatest within the first hour. The majority of cases have occurred within the first 3 hours after injection; however the event has occurred after 3 hours.

Visual: Nurse talking to camera

Text on screen: Observe patients for 3 hours for symptoms of PDSS

Patients should be advised of this potential risk and the need to be observed for 3 hours in a healthcare facility each time ZYPREXA RELPREVV is administered.

Patients experiencing post-injection delirium/sedation syndrome should be managed as clinically appropriate. Patients may be treated symptomatically.

If a Post-injection Delirium/Sedation Syndrome event is suspected, close medical supervision and monitoring should be conducted in a facility capable of resuscitation.

Text on screen: If parenteral benzodiazepines are required for patient management during a PDSS event, careful evaluation of clinical status for excessive sedation and cardiorespiratory depression is recommended.

If parenteral benzodiazepines are required for patient management during a PDSS event, careful evaluation of clinical status for excessive sedation and cardiorespiratory depression is recommended.
Text on Screen:
Notify hospital or ER personnel of:
• “…a probable olanzapine overdose following administration of Olanzapine For Extended Release Injectable Suspension.”

If the patient is sent to a hospital or ER for further observation or management, notify the hospital or ER personnel that the patient is experiencing “a probable olanzapine overdose following administration of Olanzapine For Extended Release Injectable Suspension.”

Text on Screen:
Important:
Before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection.

An important reminder: before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection.

Text on Screen:
After each injection:
• Patients should be observed for at least 3 hours by appropriately qualified personnel in a healthcare facility with ready access to emergency response services
• The patient should be located where he or she can be seen and/or heard at all times

After each ZYPREXA RELPREVV injection:
• Patients should be observed for at least 3 hours by appropriately qualified personnel in a healthcare facility with ready access to emergency response services
• The patient should be located where he or she can be seen and/or heard at all times

Text on Screen:
Before patient leaves the healthcare facility:
• Confirm that the patient is alert, oriented, and without signs or symptoms of a post-injection delirium/sedation syndrome event
• Advise patients and their caregivers to be vigilant for symptoms of a post-injection delirium/sedation syndrome event for the remainder of the day and to be able to obtain assistance if needed
• All patients should be accompanied to their next destination upon leaving the facility

Before the patient leaves the healthcare facility:
• Confirm that the patient is alert, oriented, and without signs or symptoms of a post-injection syndrome event
• Advise patients and their caregivers to be vigilant for symptoms of a post-injection syndrome event for the remainder of the day and be able to obtain assistance if needed
• All patients should be accompanied to their next destination upon leaving the facility

Text on Screen:
After patient leaves the healthcare facility:
• Patients should not drive or operate heavy machinery for the remainder of the day

After leaving the healthcare facility, patients should not drive or operate heavy machinery for the remainder of the day.

Visual:
Nurse talking to camera

In addition, patient ID cards and wristbands are available for distribution to patients who receive ZYPREXA RELPREVV. The patient ID cards can be used to record the date and time of injection, concomitant medications, and emergency contact information. The wristbands can be used to note the date of the injection and an emergency contact number. Please contact your Lilly sales representative to receive a supply of patient ID cards and wristbands to use in your treatment facility.
### Text on-Screen:
Increased contact with blood can occur:
- Partial injection into vasculature
- Significant vessel injury during IM injection (nick or puncture)
- Substantial bleeding at injection site

**ZYPREXA RELPREVV** is much more soluble in blood than in muscle. Increased contact with a substantial volume of blood could occur in several ways, such as:
- Partial injection into vasculature
- Vessel injury associated with the intramuscular injection (a nick or puncture of the blood vessel)
- And substantial bleeding at injection site

### Text on-Screen:
Deep intramuscular gluteal injection:
- Intended for deep muscular gluteal injection only
  - Not for intravenous, subcutaneous, or deltoid injection
- Aspirate syringe prior to injection to ensure no blood is visible
- If blood is visible, discard the syringe and use a new product kit

Therefore, **ZYPREXA RELPREVV** is intended for deep intramuscular gluteal injection only. It is important to aspirate the syringe prior to injection to ensure no blood is visible. Administrators must not proceed with the injection if blood is visible. If blood is visible, discard the syringe and use a new product kit.

### Visual:
Nurse talking to camera

**Post-Injection Delirium/Sedation Syndrome** can occur at any injection, so safety precautions should be observed every time the product is administered.

### Step 1 – Prepare Materials

<table>
<thead>
<tr>
<th>Text on-screen</th>
<th>Visual</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZYPREXA RELPREVV logo</td>
<td>Nurse talking to camera</td>
</tr>
<tr>
<td>Chapter Three</td>
<td></td>
</tr>
<tr>
<td>Step 1 – Prepare Materials</td>
<td>Let’s begin by preparing for the ZYPREXA RELPREVV injection.</td>
</tr>
<tr>
<td><strong>Visual:</strong> Nurse talking to camera</td>
<td>First, you will need to gather and prepare your materials.</td>
</tr>
<tr>
<td><strong>Visual:</strong> Pair of hands placing gloves and alcohol wipes on counter.</td>
<td>Obtain 1 pair of gloves, several alcohol wipes, and the prescribed dose of ZYPREXA RELPREVV.</td>
</tr>
<tr>
<td><strong>Visual:</strong> Nurse talking to camera</td>
<td>The medication comes packaged in a convenience kit that includes the following items:</td>
</tr>
<tr>
<td><strong>Visual:</strong> Pair of hands placing contents of kit (vial of powder, vial of diluent, Needle-Pro® 3ml syringe with safety needle, 2 additional safety needles) on counter.</td>
<td>A vial of ZYPREXA RELPREVV powder; a 3ml vial of diluent, one Needle-Pro® 3ml syringe with attached 19 gauge, 1.5 inch safety needle, 2 additional 19 gauge, 1.5 inch safety needles, a Reconstitution and Administration leaflet, and a patient Medication Guide.</td>
</tr>
<tr>
<td><strong>Visual:</strong> Nurse talking to camera</td>
<td>Open the kit, remove all items, and arrange them conveniently to prepare for reconstitution</td>
</tr>
<tr>
<td><strong>Visual:</strong> Pair of hands putting on gloves</td>
<td>You will need to wear gloves when reconstituting ZYPREXA RELPREVV, as the medication can be irritating to the skin.</td>
</tr>
<tr>
<td><strong>Visual:</strong> Nurse talking to camera</td>
<td>If the medication contacts skin, flush it with water.</td>
</tr>
</tbody>
</table>
### Step 2 – Determine Reconstitution Volume

<table>
<thead>
<tr>
<th>Text on screen:</th>
<th>Music</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZYPREXA RELPREV logo</td>
<td>Chapter Four</td>
</tr>
<tr>
<td>Step 2 – Determine Reconstitution Volume</td>
<td>Visual: Nurse talking to camera</td>
</tr>
</tbody>
</table>

Next you will need to determine the reconstitution volume.

| Visual: C/U of table on reconstitution and administration instructions | Please refer to the table in the full-color reconstitution and administration instructions for the proper volumes of diluent to add for each vial strength. For example, if you are preparing a 210mg dose, you will need to add 1.3ml of diluent to the 210mg powder vial. |

| Visual: Nurse talking to camera | Visual: Nurse talking to camera |

There will be excess diluent remaining in the vial. It is important to note that no matter what dose you are preparing, there will be excess diluent remaining in the vial. This extra diluent will not be needed.

### Reconstitute

<table>
<thead>
<tr>
<th>Text on screen: ZYPREXA RELPREV logo</th>
<th>Music</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter Five</td>
<td>Visual: Nurse talking to camera</td>
</tr>
</tbody>
</table>

Now you are ready to reconstitute ZYPREXA RELPREV. The process of reconstitution and administration should take around 5 minutes to complete.

| Visual: Hands tapping powder vial and wiping vials with alcohol wipes | First, loosen the powder by lightly tapping the vial a few times. The powder should be free flowing. This step helps to ensure the powder suspends easily and thoroughly after the diluent is added. |

| Visual: Hands withdrawing diluent into syringe | Withdraw the proper amount of diluent into the syringe. In this case, the vial strength is 210mg, so we will withdraw 1.3ml of solution. |

| Visual: Hands injecting diluent into powder vial | Inject the diluent into the powder vial. Before you withdraw the needle, pull back on the plunger to withdraw some air. This will help equalize pressure in the vial. Hold the vial upright when removing the needle to prevent any loss of medication. Next, engage the safety needle and push the air out of the syringe. |

| Visual: Hands tapping the vial | The suspension must be mixed correctly to ensure proper dosing. Tap the vial firmly and repeatedly on a hard, cushioned surface until there is no powder visible. Avoid shaking the vial before tapping, as this can make it more difficult to suspend. |

| Text on screen: Tap firmly and repeatedly | Visual: Hands tap and shake vial |

Check for clumps by inspecting the sides and bottom of the vial. Unsuspended powder appears as light yellow, dry clumps clinging to the vial.
<table>
<thead>
<tr>
<th>Visual: C/U of suspension</th>
<th>If clumps are visible, tap the vial again to break the clumps free. Shake the vial vigorously until the suspension appears smooth and consistent in color and texture.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual: Hands continue to shake, tap and inspect vial</td>
<td>Sometimes foam will form from shaking the vial. The foam will dissipate if you let the vial stand briefly. You should avoid drawing foam up into the syringe, as the excess air bubbles are hard to remove and may affect the accuracy of the dose.</td>
</tr>
<tr>
<td>Visual: Nurse talking to camera</td>
<td>Once reconstituted, the suspension is stable in the vial for up to 24 hours and does not require refrigeration. However, if the suspension is not used immediately, it should be shaken to resuspend before being drawn into the syringe for administration. Once drawn up into the syringe, this medication should be injected immediately.</td>
</tr>
<tr>
<td>Text on screen: Product is stable in the vial for 24 hours after reconstitution.</td>
<td>Once reconstituted, the suspension is stable in the vial for up to 24 hours and does not require refrigeration. However, if the suspension is not used immediately, it should be shaken to resuspend before being drawn into the syringe for administration. Once drawn up into the syringe, this medication should be injected immediately.</td>
</tr>
</tbody>
</table>

**Inject ZYPREXA RELPREVV**

<table>
<thead>
<tr>
<th>Text on screen: ZYPREXA RELPREVV logo</th>
<th>Music</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter Six</td>
<td>Inject ZYPREXA RELPREVV</td>
</tr>
</tbody>
</table>

**Visual: Hands attaching new safety needle**

Attach a new safety needle to the syringe.

For all doses, the concentration of olanzapine in the suspension is 150 mg per 1 ml.

**Visual: C/U of table of instructions**

When preparing to draw up the prescribed dose, refer to the table in the instructions for the correct injection volume.

For a prescribed dose of 210mg, you will withdraw 1.4ml from the reconstituted vial.

**Visual: C/U of hands withdrawing suspension into the syringe**

To prevent the product from leaking from the stopper, do not add air to the vial. Slowly withdraw the desired amount into the syringe. By doing this slowly, you will avoid excess air bubbles being drawn into the syringe.

**Visual: Nurse talking to camera**

There will be excess medication remaining in the vial.

**Text on screen: There will be excess medication remaining in the vial**

**Visual: Hands tapping syringe**

To ensure the full dose is given, tap the syringe with your fingers to remove all excess air bubbles.

**Visual: Hands removing needle from vial, engaging safety device, and attaching new safety needle**

Once the desired dose is withdrawn, remove the needle from the vial, and engage the needle safety device.

Attach a new safety needle to the syringe.
<table>
<thead>
<tr>
<th>Text on screen:</th>
<th>Important: Prior to administration, you must make sure that the patient receiving ZYPREXA RELPREVV will be accompanied to his or her destination following the 3-hour observation period. If this cannot be confirmed, do not give the injection.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual: C/U of syringe</td>
<td>Even if accompanied, the patient may not drive to his or her destination or for the rest of the day.</td>
</tr>
<tr>
<td>Visual: Nurse talking to camera</td>
<td>For these demonstrations, we are using an anatomical model. The model is not designed to receive product, so we will be using an empty syringe to show how the injection should be administered.</td>
</tr>
<tr>
<td>Visual: C/U of anatomical model and hands giving injection</td>
<td>Now you are ready to give the injection of ZYPREXA RELPREVV. Once the medication is drawn into the syringe, it should be injected immediately.</td>
</tr>
</tbody>
</table>

### Ventrogluteal Injection

<table>
<thead>
<tr>
<th>Text on screen: ZYPREXA RELPREVV logo</th>
<th>Music</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter Seven Ventrogluteal Injection</td>
<td></td>
</tr>
<tr>
<td>Visual: C/U of practice ventrogluteal injection process on anatomical model</td>
<td>To give a ventrogluteal injection, place the heel of your hand on the greater trochanter, or hip bone at the top of the thigh. Your wrist will be in line with the person's thigh.</td>
</tr>
<tr>
<td></td>
<td>Point your thumb at the groin and fingers towards the person's head. Form a &quot;V&quot; by opening a space between your pointer finger and the other three fingers. The place to give the injection is in the middle of the V-shaped triangle.</td>
</tr>
<tr>
<td></td>
<td>Insert the needle into the muscle, then aspirate slowly for several seconds by pulling back on the plunger of the syringe.</td>
</tr>
<tr>
<td>Visual: Nurse talking to camera</td>
<td>If any blood is drawn into the syringe, discard the syringe and the dose, and begin with a new kit.</td>
</tr>
<tr>
<td>Visual: C/U on hands giving injection</td>
<td>In this case, no blood is seen, so we will inject the medication with steady pressure.</td>
</tr>
<tr>
<td>Visual: C/U of hands withdrawing needle and engaging safety device</td>
<td>After withdrawing the needle carefully from the muscle, engage the needle safety device.</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Visual: Nurse talking to camera</td>
<td>Do not massage the injection site</td>
</tr>
<tr>
<td>Visual: C/U of hands disposing vial, needle, and syringe</td>
<td>Finally, after the injection, make sure to dispose of the vials, needles, and syringe appropriately.</td>
</tr>
<tr>
<td><strong>Dorsogluteal Injection</strong></td>
<td></td>
</tr>
<tr>
<td>Text on-screen: ZYPREXA RELPREVV logo</td>
<td></td>
</tr>
<tr>
<td>Chapter Eight Dorsogluteal Injection</td>
<td></td>
</tr>
<tr>
<td>Visual: C/U of practice dorsogluteal injection process on anatomical model</td>
<td>To administer a dorsogluteal injection, first locate the upper quadrant of the buttocks by drawing an imaginary line across and down, dividing the buttocks into 4 quadrants. Insert the needle into the gluteal muscle, then aspirate slowly for several seconds by pulling back on the plunger of the syringe. If any blood is drawn into the syringe, discard the syringe and the dose, and begin with a new kit. In this case, no blood is seen, so we will inject the medication with a steady pressure.</td>
</tr>
<tr>
<td>Visual: C/U of hands withdrawing needle and engaging safety device</td>
<td>After withdrawing the needle carefully from the gluteal muscle, engage the needle safety device</td>
</tr>
<tr>
<td>Visual: Nurse talking to camera</td>
<td>Do not massage the injection site</td>
</tr>
<tr>
<td><strong>Text on-screen:</strong> Do not massage the area after the injection</td>
<td></td>
</tr>
<tr>
<td>Visual: C/U of hands disposing vial, needle, and syringe</td>
<td></td>
</tr>
<tr>
<td><strong>Text on-screen:</strong> Note: The vial is for single use only</td>
<td>Finally, after the injection, make sure to dispose of the vials, needles, and syringe appropriately.</td>
</tr>
<tr>
<td><strong>Recap</strong></td>
<td></td>
</tr>
<tr>
<td>Text on-screen: ZYPREXA RELPREVV logo</td>
<td>Music</td>
</tr>
<tr>
<td>Chapter Nine Recap</td>
<td></td>
</tr>
<tr>
<td>Visual: Nurse talking to camera</td>
<td>To summarize, the process of reconstituting and administering ZYPREXA RELPREVV can be broken down into four easy steps.</td>
</tr>
<tr>
<td>Text on-screen:</td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td></td>
</tr>
<tr>
<td>• Prepare Materials</td>
<td></td>
</tr>
<tr>
<td>• Determine Reconstitution Volume</td>
<td></td>
</tr>
<tr>
<td>• Reconstitute</td>
<td></td>
</tr>
<tr>
<td>• Inject</td>
<td></td>
</tr>
<tr>
<td>One, prepare materials;</td>
<td></td>
</tr>
<tr>
<td>two, determine reconstitution volume;</td>
<td></td>
</tr>
<tr>
<td>three, reconstitute; and</td>
<td></td>
</tr>
<tr>
<td>four, inject.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Visual:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse talking to camera</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Visual:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real-time reconstitution process with timer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Text on Screen:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-800-LillyRx</td>
</tr>
<tr>
<td>(1-800-545-5979)</td>
</tr>
<tr>
<td><a href="http://www.ZyprexaRelprev.com">www.ZyprexaRelprev.com</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Narrator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Watch as we demonstrate the entire process in real time. Remember, for these demonstrations, we are using an anatomical model. The model is not designed to receive product, so we will be using an empty syringe to show how the injection should be administered.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Music</th>
</tr>
</thead>
</table>

| Reference ID: 4417451 |
SINGLE PATIENT INJECTION FORM

IMPORTANT: Before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection.

Submit this information within 7 days after the patient’s injections. If you are aware that the patient's prescriber has changed, please notify the ZYPREXA RELPREVV Patient Care Program Coordinating Center.

Patient No.: [ ] [ ] [ ] [ ] [ ] [ ]
Injection Facility Name: ______________________

Patient Name:
First
MI
Last

Date of Birth: [ ] [ ] [ ] [ ] [ ] [ ] [ ]
month day year

PDSS since the last visit? (After the patient left the office, following his/her previous injection, did the patient experience post-injection delirium/sedation syndrome?)

☐ No  ☐ Yes
If Yes, has the prescriber been notified of the PDSS event?

☐ Yes  ☐ No

ZYPREXA RELPREVV TREATMENT

Date of Injection: [ ] [ ] [ ] [ ] [ ] [ ]
month day year

Time of ZYPREXA RELPREVV injection: [ ] [ ] : [ ] [ ] 24-hour clock

Dose of Injection: ☐ 150 mg  ☐ 210 mg  ☐ 300 mg  ☐ 405 mg  ☐ Other dose ________ mg

Was the patient observed for at least 3 hours post-injection? ☐ Yes  ☐ No

Did the patient experience post-injection delirium/sedation syndrome during the onsite post-injection observational period?

☐ No  ☐ Yes
If Yes, has the prescriber been notified of the PDSS event? ☐ Yes  ☐ No

Following the injection, was the patient alert, oriented, and absent of any signs and symptoms of PDSS prior to being released from the healthcare facility?

☐ Yes  ☐ No

Following the injection, was the patient accompanied from the facility?

☐ Yes  ☐ No  ☐ Not applicable, patient did not leave facility (in-patient)

Was the patient or legal guardian given a Medication Guide prior to this injection? ☐ Yes  ☐ No

Healthcare Facility Staff Member Signature: ______________________

DATE: [ ] [ ] [ ] [ ] [ ] month day year

Healthcare Facility Staff Member Name (print): ______________________

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Reference ID: 4417451
MULTIPLE PATIENT INJECTION FORM

IMPORTANT: Before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection. Submit this information within 7 days after the patient's injection. If you are aware that the patient's prescriber has changed, please notify the ZYPREXA RELPREVV Patient Care Program Coordinating Center.

Injection Facility Name: 

Date of Injection: [month] [day] [year]

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name:</td>
<td></td>
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</tr>
<tr>
<td>First Name</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Last Name</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Date of Birth: [month] [day] [year]

PDSS since last visit? (check one) 
- Yes
- No

If Yes, has the prescriber been notified of the PDSS event? 
- Yes
- No

Time of Injection (24-hour clock): [hour] [minute]

Dose of Injection (check one) 
- 150 mg
- 210 mg
- 300 mg
- 405 mg
- Other dose [mg]

Observed at least 3 hours post-injection? (check one) 
- Yes
- No

PDSS during onsite observation? (check one) 
- Yes
- No

If Yes, has the prescriber been notified of the PDSS event? 
- Yes
- No

Following the injection, was the patient alert, oriented, and absent of any signs and symptoms of PDSS prior to being released from the healthcare facility? (check one) 
- Yes
- No

Following the injection, was the patient accompanied from the facility? (check one) 
- Yes
- No

Not applicable, patient did not leave facility (in-patient)

Signature: 

Healthcare Facility Staff Member Signature: [month] [day] [year]

Healthcare Facility Staff Member Name (print): 

Was the patient or legal guardian given a Medication Guide prior to this injection? 
- Yes
- No

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Version 2.0 5/3/2012 CONFIDENTIAL

Reference ID: 4188742
PATIENT REGISTRATION FORM COPY

PATIENT INFORMATION

First Name: ___________________________ MI: ______ Last Name: ___________________________

Date: ___________________________

PATIENT AGREEMENT

The maker of ZYPREXA RELPREVV, Eli Lilly and Company and their delegates run the ZYPREXA RELPREVV Patient Care Program. Your doctor will send your name, date of birth, and other information that directly identifies you to the ZYPREXA RELPREVV Patient Care Program. Ask your doctor if you have questions about the information that will be collected.

The ZYPREXA RELPREVV Patient Care Program will collect and use your information in the following ways:

- Your doctor will provide dose, date and time of each injection, and other medical information to the ZYPREXA RELPREVV Patient Care Program.
- Your information will be stored in the ZYPREXA RELPREVV Patient Care Program computer system.
- The information will be used to help Lilly learn more about the safety of ZYPREXA RELPREVV.
- Information from all patients in the ZYPREXA RELPREVV Patient Care Program will be reviewed and may be combined with information from clinical studies.
- This combined information will not be able to identify you or any other patient. This combined information may be shared with:
  - regulatory agencies,
  - doctors at other institutions,
  - the committee overseeing the ZYPREXA RELPREVV Patient Care Program, and/or
  - publications or as part of scientific discussions.

Also, by signing this form you agree to the following:

- I understand that I must enroll in the ZYPREXA RELPREVV Patient Care Program registry to get ZYPREXA RELPREVV.
- I agree to have my information entered in the ZYPREXA RELPREVV Patient Care Program registry.
- My doctor has explained the risks and benefits of treatment with ZYPREXA RELPREVV.
- I have received a copy of the Medication Guide.
- I understand that I will be observed at the clinic for 3 hours after each injection.
- Someone must go with me to my destination when I leave the clinic.
- I understand that I can not drive or use heavy machinery for the rest of the day on which I get an injection.
- I agree to seek medical care right away if I have a reaction such as excessive sleepiness, dizziness, confusion, difficulty talking, difficulty walking, muscle stiffness or shaking, weakness, irritability, aggression, anxiety, increase in blood pressure or convulsions.
- I agree to contact my doctor if I have a reaction to ZYPREXA RELPREVV.
- I may be asked to complete occasional surveys about my understanding of the risks and benefits of treatment with ZYPREXA RELPREVV.
- I or my caregiver have discussed any questions or concerns about my treatment with ZYPREXA RELPREVV with my doctor.

You may stop participating in the ZYPREXA RELPREVV Patient Care Program at any time by telling your doctor. If you stop participating, you will no longer be able to receive the drug. Your doctor will no longer provide any of your information to the ZYPREXA RELPREVV Patient Care Program except to answer safety questions. The ZYPREXA RELPREVV Patient Care Program will still use information that was collected before you stopped participating. You will be provided a copy of this form.
POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Submit this information within 24 hours of becoming aware of a suspected PDSS event.

Patient No.: [Blank]
(PIN)

Patient Name: __________________________

First Name __________________________
MI __________________________
Last Name __________________________

Date of Birth: ________-____-________
month day year

Does the patient have a diagnosis of schizophrenia? ☐ Yes ☐ No

PATIENT/INJECTION INFORMATION

Date of Injection: ________-____-________
month day year

Time of ZYPREXA RELPREVIV Injection: ________ : ________

Convenience Kit Package

Lot # __________________________

ONSET OF FIRST PDSS SYMPTOM AFTER INJECTION (choose only one)

☐ 1 - 15 minutes ☐ 46 - 60 minutes ☐ 121 - 150 minutes (2 1/2 hours)
☐ 16 - 30 minutes ☐ 61 - 90 minutes (1 1/2 hours) ☐ 151 - 180 minutes (3 hours)
☐ 31 - 45 minutes ☐ 91 - 120 minutes (2 hours) ☐ If greater than 3 hours please specify:

__________ Hours

Dose of Injection: ☐ 150 mg ☐ 210 mg ☐ 300 mg ☐ 405 mg ☐ Other dose ______ mg

Was the injection given in gluteal muscle? ☐ Yes ☐ No

Height: (inches) ________
Weight: (lbs.) ________

PDSS SIGNS AND SYMPTOMS

Please mark the signs and symptoms that the patient experienced (check all that apply).

☐ Aggressiveness ☐ Coma ☐ Hypertension ☐ Tachycardia
☐ Agitation ☐ Confusion ☐ Hypotension ☐ Various extrapyramidal symptoms
☐ Anxiety ☐ Convulsion/Seizure ☐ Other cognitive impairment ☐ Weakness
☐ Aspiration ☐ Delirium ☐ Possible neuroleptic malignant syndrome ☐ Other _________
☐ Ataxia ☐ Disorientation ☐ Reduced level of consciousness ☐ Other _________
☐ Cardiac arrhythmias ☐ Dizziness ☐ Respiratory depression ☐ Other _________
☐ Cardiopulmonary arrest ☐ Dysarthria ☐ Sedation ☐ Other _________

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POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.: □□□□□□
(PIN)

Patient Name: ____________________________________________
First Name ____________________________________________ MI ______ Last Name ____________________________________________

PDSS start date: _______ _______ ______
month day year

PDSS resolution date: _______ _______ ______
month day year OR □ Ongoing

If resolved, duration of PDSS: ____________________________ □ Minutes □ Hours □ Days

Are these PDSS symptoms related to ZYPREXA RELPREVY?
☐ Yes
☐ No - Please Explain ________________________________

Describe the clinical course ____________________________________________

Patient Outcome: (choose one)
□ Recovered □ Fatal
□ Unknown □ Recovering □ Not Recovered
□ Recovered with sequelae

Once a PDSS event was suspected, was the patient’s monitoring initiated in a facility capable of resuscitation? □ Yes □ No

Did the patient visit the emergency room as a result of the PDSS? □ Yes □ No

Was the patient admitted to the hospital as a result of the PDSS? □ Yes □ No

Were olanzapine concentrations collected? □ Yes □ No

Did the patient receive any MEDICATION AS TREATMENT for the PDSS event? □ Yes - Please record below □ No

<table>
<thead>
<tr>
<th>Treatment Medication Name</th>
<th>Dose</th>
<th>Duration of Use (in Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

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POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.: □ □ □ □ □

Patient Name:
First Name
MI
Last Name

Did the patient receive any NON-PHARMACEUTICAL TREATMENTS or DIAGNOSTIC TESTS associated with this event? □ Yes - Please record below □ No

☐ Assisted ventilation ☐ EEG ☐ MRI
☐ Brain CT ☐ IV fluids ☐ Observation/symptomatic management
☐ ECG ☐ Labs ☐ Restraints
☐ Other ______

Please fax test results to 1-877-772-9391.

HISTORY PRIOR TO PDSS EVENT

Does the patient have any relevant comorbidities?
□ Yes - Please specify: __________________________
□ No

PRIOR MEDICATIONS

Did the patient take any medications during the 24 hours prior to the injection? □ Yes - Please record below □ No

<table>
<thead>
<tr>
<th>Prior Medication Name</th>
<th>Dose</th>
<th>Duration of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Number</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Days</td>
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<tr>
<td></td>
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<td>Days</td>
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<td>Days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Days</td>
</tr>
</tbody>
</table>

Did the patient use any of the following during the 24 hours prior to the injection? □ Yes - Please record below □ No

☐ Alcohol
☐ Barbiturates
☐ Cocaine
☐ Opiates
☐ Amphetamines/Methamphetamines
☐ Cannabinoid
☐ Hallucinogens
☐ Phencyclidine

Event reported by: __________________________
First
MI
Last

Title/Occupation: __________________________

If agent of the Prescriber, name of Prescriber: __________________________

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Welcome to the ZYPREXA RELPREVV Patient Care Program

The goal of the ZYPREXA RELPREVV Patient Care Program is to mitigate the risk of negative outcomes associated with ZYPREXA RELPREVV post-injection delirium/sedation syndrome (PDSS).

For a tour of the ZYPREXA RELPREVV Patient Care Program system click here.

On-line Training  Prescribing Information  Log In
Registration Forms  Medication Guide  Contact Us
Order Educational Materials  Pharmacy Finder

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVV, including Boxed Warnings.

This site is intended for U.S. residents age 18 and over.
For more information about ZYPREXA RELPREVV, contact your doctor or other healthcare professional.
ON-LINE TRAINING

Select your role(s) from the list below to access required training.

Prescriber

Healthcare Facility Staff

Pharmacy Service Providers (pharmacies and buy & bill pharmacy service providers)
Required Prescriber Training

1. ZYPREXA RELPREVV Patient Care Program Instructions Brochure
2. Healthcare Professional Training (select one)
   - Slide Presentation
   - OR
   - Recorded Presentation

Additional Resources

Post-Injection Delirium/Sedation Syndrome Case Study Video

Once you have completed the required training, submit the appropriate registration form.
Required Prescriber Training

1. ZYPREXA RELPREVVL Patient Care Program
2. Healthcare Professional Training
   - Slide Presentation
   OR
   - Recorded Presentation

ADDITIONAL RESOURCES

Post-Injection Delirium/Sedation Symptoms

Once you have completed the required training, you will be able to access the following resources:

PRIVACY POLICY | TERMS OF USE

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVVL.

This site is intended for U.S. residents age 18 and older.

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ZYPREXA RELPREVVL Patient Care Program Instructions Brochure

ZYPREXA RELPREVVL (olanzapine) For Extended Release Injectable Suspension
Required Prescriber Training

1. ZYPREXA RELPREVV
2. Healthcare Professional
   - Slide Presentation
   - Recorded Presentation

ADDITIONAL RESOURCES

Post-Injection Delirium/Sedation

Once you have completed the required training, you can access additional resources.

PRIVACY POLICY

TERMS OF USE

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVV.

This site is intended for U.S. residents age 18 and over.

For more information about ZYPREXA RELPREVV, contact your doctor or pharmacist.

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Version: 1.27.A. FR-00-03-0857. 04/2017
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The goal of this presentation is to educate healthcare professionals in an effort to mitigate negative outcomes associated with ZYPREXA RELPREVV post-injection delirium/sedation syndrome (PDSS).

Healthcare professionals include: physicians, nurses and any other professionals who will be involved with the care of the patient receiving the injection.

Please see the Prescribing Information and the Reconstitution and Administration Poster before using ZYPREXA RELPREVV.
ZYPREXA RELPREVV Patient Care Program

Required Prescriber Training

1. ZYPREXA RELPREVV Patient Care Program
2. Healthcare Professional Training
   • Slide Presentation
   OR
   • Recorded Presentation

ADDITIONAL RESOURCES

Post-Injection Delirium/Sedation Syndrome Case
Once you have completed the required training, submit

ZYPREXA® RELPREVV™
(olanzapine) For Extended Release Injectable Suspension
Training for Healthcare Professionals

Please see the Prescribing Information and the Reconstitution and Administration Poster before using ZYPREXA® RELPREVV™
Required Healthcare Facility Staff Training

- REQUIRED TRAINING FOR STAFF ADMINISTERING INJECTIONS AND STAFF WHO MONITOR PATIENTS
  1. Healthcare Professional Training (select one)
     - Slide Presentation
     - OR
     - Recorded Presentation
  2. ZYPREXA RELPREVIV Patient Care Program Instructions Brochure
- REQUIRED ADDITIONAL TRAINING FOR STAFF ADMINISTERING INJECTIONS
  3. Reconstitution & Administration Instruction
     - Training Video
     - AND
     - Poster (view and/or print)

ADDITIONAL RESOURCES

Post-Injection Delirium/Sedation Syndrome Case Study Video

Once all the appropriate staff from a healthcare facility have completed the required training, a representative from the facility must submit the Healthcare Facility Registration Form.
Required Healthcare Facility Staff Training

1. **Healthcare Professional Training** (select one)
   - **Slide Presentation**
   
   OR

---

**ZYPREXA RELPREVX Patient Care Program**

Training Presentation

**ZYPREXA RELPREVX**
(olanzapine) For Extended Release Injectable Suspension

Training for Healthcare Professionals

The goal of this presentation is to educate healthcare professionals in an effort to mitigate negative outcomes associated with ZYPREXA RELPREVX post-injection delirium/sedation syndrome (PDSS). Healthcare professionals include: physicians, nurses and any other professionals who will be involved with the care of the patient receiving the injection.

Please see the Prescribing Information and the Reconstitution and Administration Poster before using ZYPREXA RELPREVX.
ZYPREXA RELPREVV Patient Care Program

Required Healthcare Facility Staff Training

ZYPREXA RELPREVV Patient Care Program Instructions Brochure

Zyprexa

(olanzapine) For Extended Release Injectable Suspension
Reference ID: 4417451

ZYPREXA RELPREVV Patient Care Program

**Required Healthcare Facility Staff Training**

- **REQUIRED TRAINING FOR STAFF ADMINISTERING INJECTIONS AND STAFF WHO MONITOR PATIENTS**

1. Reconstitution & Administration Instruction...

2. ZYPREXA Relprevv (olanzapine) for Extended Release Injectable Suspension

3. ZYPREXA RELPREVV RECONSTITUTION AND ADMINISTRATION TRAINING

**Additional**

Post-Injection Delirium/Sedation Syndrome Case Study Video

Once all the appropriate staff from a healthcare facility have completed the required training, a representative from the facility must submit the Healthcare Facility Registration Form.

**Privacy Policy**

**Terms of Use**

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVV, including Boxed Warnings.

This site is intended for U.S. residents age 18 and over.

For more information about ZYPREXA RELPREVV, contact your doctor or other healthcare professional.

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Version: 1.37.0, PP-DD-US-007 04/2017

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ZYPREXA RELPREVV Patient Care Program

Required Healthcare Facility Staff Training

1. Healthcare Professional Training (select one)

Instructions to Reconstitute and Administer ZYPREXA RELPREVV

FOR DEEP INTRAMUSCULAR GLUTEAL INJECTION ONLY.
NOT TO BE INJECTED INTRAVENOUSLY OR SUBCUTANEOUSLY.

For Important Safety Information, including boxed warnings, see the full Prescribing Information provided.

STEP 1 PREPARING MATERIALS

Convenience kit includes:

- Vial of ZYPREXA RELPREVV powder
- 5-mL vial of diluent
- One 5-mL syringe with pre-attached 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro®
- Needles with needle protection device
- Two 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needles with needle protection device.
- For obese patients, a 2-inch (50 mm) 16-gauge or larger needle (not included in convenience kit) may be used for administration.

ZYPREXA RELPREVV must be suspended using only the diluent supplied in the convenience kit.

It is recommended that gloves are used when reconstituting, as ZYPREXA RELPREVV may be irritating to the skin. Wash with water if contact is made with skin.

STEP 2 DETERMINING RECONSTITUTION VOLUME

Refer to the table at left to determine the amount of diluent to be added to powder for reconstitution of each vial strength.

It is important to note that there is more diluent in the vial than is needed to reconstitute.

STEP 3 RECONSTITUTING ZYPREXA RELPREVV

9.1 Loosen the vial by lightly tapping the vial.
9.2 Open the prepackaged Hypodermic Needle-Pro syringes and needles with needle protection device.
9.3 Withdraw the non-determined diluent volume (that is, into the syringe.)

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Once all the appropriate staff from a healthcare facility have completed the required training, a representative from the facility must submit the Healthcare Facility Registration Form.
1. **ZYPREXA RELPREVV Patient Care Program Instructions Brochure**

   It is the responsibility of the pharmacy service provider representative to assure that all staff involved with dispensing ZYPREXA RELPREVV have reviewed the ZYPREXA RELPREVV Patient Care Program Instructions Brochure prior to submitting one of the registration forms below.

   - **Pharmacy Registration Form**
   
   OR

   - **Buy & Bill Pharmacy Service Provider* Registration Form**

* Buy & Bill Pharmacy Service Provider - a licensed healthcare provider that purchases pharmaceuticals through a licensed distributor for its own use in the treatment of a patient and then includes the cost of the pharmaceutical in its billing of patients and third-party payers.
ZYPREXA RELPREVV Patient Care Program

Required Pharmacy Service Provider Training

ZYPREXA RELPREVV Patient Care Program Instructions Brochure

Zyrexa Relprevv
(olanzapine) For Extended Release Injectable Suspension
Prior to selecting and completing a registration form listed below, please ensure you have completed the appropriate training. To complete training on-line, select the "On-line Training" link below, or to receive materials in hard copy, select the "Order Educational Materials" link below.

Prescriber Registration Form
Pharmacy Registration Form
Buy & Bill Pharmacy Service Provider Registration Form
Patient Registration Form
  * Patient Copy
Healthcare Facility Registration Form

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Registration Forms

Prior to selecting and completing a registration form listed below, please ensure you have completed the appropriate training. To complete training on-line, select the "On-line Training" link below, or to receive materials in hard copy, select the "Order Educational Materials" link below.

Prescriber Registration Form
Pharmacy Registration Form
Buy & Bill Pharmacy Service Provider Registration
Patient Registration Form
  • Patient Copy
Healthcare Facility Registration Form

Do you want to complete your registration on-line or print a registration form?

On-line  Print

Privacy Policy  Terms of Use

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVVE, including Boxed Warnings.
This site is intended for U.S. residents age 18 and over.
For more information about ZYPREXA RELPREVVE, contact your doctor or other healthcare professional.

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By signing below, I acknowledge that:

- I understand the ZYPREXA RELPREVV Patient Care Program requirements and the risks associated with ZYPREXA RELPREVV.
- I have completed the mandatory ZYPREXA RELPREVV training.
- I understand the clinical presentation of post-injection delirium/sedation syndrome (PDSS) and how to manage patients should an event occur while using ZYPREXA RELPREVV;
- I understand that ZYPREXA RELPREVV should only be initiated in patients for whom tolerability with oral olanzapine has been established;
- I understand that ZYPREXA RELPREVV should only be administered to patients in healthcare settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.
- I will enroll all patients in the ZYPREXA RELPREVV Patient Care Program registry prior to prescribing ZYPREXA RELPREVV by completing the Patient Registration Form.
- I will ensure all suspected cases of PDSS are reported to the ZYPREXA RELPREVV Patient Care Program within 24 hours of becoming aware of the event.
- I will review the ZYPREXA RELPREVV Medication Guide with each patient prior to prescribing.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact me to resolve discrepancies, to obtain information about a patient, or to conduct occasional surveys.

I may cancel this registration by notifying the ZYPREXA RELPREVV Patient Care Program Coordinating Center by fax at 1-877-772-9391® or by phone at 1-877-772-9390®.

If I revoke my registration, I will no longer be eligible to prescribe ZYPREXA RELPREVV.

Lilly may disenroll prescribers that are non-compliant with the program requirements.

I, attest that I am the Prescriber, and understand that by clicking submit the information provided on this form is true and accurate.
By signing below, I acknowledge that:

- I understand the ZYPREXA RELPREVV Patient Care Program requirements and the risks associated with ZYPREXA RELPREVV.
- I have completed the mandatory ZYPREXA RELPREVV training.
- I understand the clinical presentation of post-injection delirium/sedation syndrome (PDSS) and how to manage patients should an event occur while using ZYPREXA RELPREVV.
- I understand that ZYPREXA RELPREVV should only be initiated in patients for whom tolerability with oral olanzapine has been established.
- I understand that ZYPREXA RELPREVV should only be administered to patients in healthcare settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.
- I will enroll all patients in the ZYPREXA RELPREVV Patient Care Program registry prior to prescribing ZYPREXA RELPREVV by completing the Patient Registration Form.
- I will ensure all suspected cases of PDSS are reported to the ZYPREXA RELPREVV Patient Care Program within 24 hours of becoming aware of the event.
- I will review the ZYPREXA RELPREVV Medication Guide with each patient prior to prescribing.
- I understand that the ZYPREXA RELPREVV Patient Care Program is a comprehensive program designed to provide support and resources to healthcare professionals and patients.

I may cancel this registration by notifying the ZYPREXA RELPREVV Patient Care Program at 1-877-772-9391 or by phone at 1-877-772-9390.

If I revoke my registration, I will no longer be eligible to prescribe ZYPREXA RELPREVV.

Lilly may disenroll prescribers that are non-compliant with the program requirements.

- I, attest that I am the Prescriber, and understand that by clicking submit the information provided on this form is true and accurate.
PRESERVER REGISTRATION FORM

To be enrolled in the ZYPREXA RELPREV Patient Care Program, complete and fax this form to 1-877-773-6391. Training must be completed before a prescriber may be enrolled in the ZYPREXA RELPREV Patient Care Program.

PRESERVER INFORMATION

First Name: ___________________________ Last Name: ___________________________
Degree: MD  DO  NP  PA  Nurse with prescriptive authority  Other with prescriptive authority
License Number: ___________________________ State of issue: ___________________________
Treatment Facility/Practice (Where you see your patients) ___________________________
If you see your patients at multiple locations please contact the ZYPREXA RELPREV Patient Care Program Coordinating Center to provide additional facility/practice information.
Address Line 1: ___________________________
Address Line 2: ___________________________
City: ___________________________ State: ___________________________ Zip: ___________________________
Phone: ___________________________ Alternate Phone: ___________________________
Fax: ___________________________ Prescriber Email: ___________________________

Preferred Method of Communication: □ Email  □ Fax

PRESERVER AGREEMENT

By signing below, I acknowledge that:
• I understand the ZYPREXA RELPREV Patient Care Program requirements and the risks associated with ZYPREXA RELPREV.
• I have completed the mandatory ZYPREXA RELPREV training.
• I understand the clinical presentation of post-injection dizziness/sedation syndrome (PIDS) and how to manage patients should an event occur while using ZYPREXA RELPREV.
• I understand that ZYPREXA RELPREV should only be initiated in patients for whom tolerability with oral olanzapine has been established.
Registration Forms

Prior to selecting and completing a registration form listed below, please ensure you have completed the appropriate training. To complete training on-line, select the “On-line Training” link below, or to receive materials in hard copy, select the “Order Educational Materials” link below.

Prescriber Registration Form
Pharmacy Registration Form
Buy & Bill Pharmacy Service Provider Registration
Patient Registration Form
  • Patient Copy
Healthcare Facility Registration Form

Do you want to complete your registration on-line or print a registration form?

[Online] [Print]
**PHARMACY REGISTRATION FORM**

To be enrolled in the ZYPREXA RELPREVX Patient Care Program, complete this form. Training must be completed before a pharmacy may be enrolled in the ZYPREXA RELPREVX Patient Care Program.

### PHARMACY INFORMATION

- **Enrollment** ☐  **Reenrollment** ☑
- **Pharmacy/Hospital Name:**
- **Pharmacy DEA Number:**
- **Please specify description of Pharmacy:**
  - ☐ Community / Retail
  - ☐ Specialty Pharmacy
  - ☐ Hospital or Institution
  - ☑ Other
- **Address Line 1:**
- **Address Line 2:**
- **City:**
- **State:**
- **Zip:**
- **Primary Phone:** ( ) ______
- **Secondary Phone:** ( ) ______
- **Fax:** ( ) ______

### SHIP TO INFORMATION

- **Ship To Address (If the same as above check here)** ☐
- **Ship To Contact Name:**
- **Address Line 1:**
- **Address Line 2:**
- **City:**
- **State:**
- **Zip:**
I will ensure that pharmacy staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to dispensing each prescription/refill by accessing the system.

I will ensure that pharmacy staff will not dispense ZYPREXA RELPREVV directly to patients.

I will ensure pharmacy staff report the date of each ZYPREXA RELPREVV dispensing to the ZYPREXA RELPREVV Patient Care Program.

For each dispense I will ensure prescription verification (includes patient eligibility check and recording the dispense date) is completed on the date of dispense, prior to the convenience kit leaving the pharmacy.

I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the pharmacy to clarify information provided or to obtain information about the patient.

I may cancel this registration by notifying the ZYPREXA RELPREVV Patient Care Program Coordinating Center by fax at 1-877-772-9390 or by phone at 1-877-772-9390. If I cancel, Lilly will cease to supply ZYPREXA RELPREVV to the pharmacy.

☐ I, attest that I am the Pharmacist-In-Charge, and understand that by clicking submit the information provided on this form is true and accurate

Confirm DEA #:  

Submit  Cancel
Reference ID: 4417451
Address Line 1: 
Address Line 2: 
City: 
State: 
Zip: 
Primary Phone: 
Secondary Phone: 
Fax: 

PHARMACIST IN CHARGE INFORMATION
First Name: 
M: 
Last Name: 
Email: 
Phone: 
Fax: 

PHARMACIST IN CHARGE INFORMATION
By signing below I acknowledge that:
- I have read and understand the ZYPREXA RELPREV Patient Care Program Instructions Brochure.
- I will ensure that all pharmacy staff are trained and have read and understand the ZYPREXA RELPREV Patient Care Program Instructions Brochure.
- I will ensure that all pharmacy staff understand ZYPREXA RELPREV can only be dispensed for use in certain health care settings e.g., hospital, clinic that have many access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.
- I will ensure that pharmacy staff will verify that the patient is enrolled in the ZYPREXA RELPREV Patient Care Program registry prior to dispensing each prescription and by accessing the system.
- I will ensure that pharmacy staff will not dispense ZYPREXA RELPREV directly to patients.
- I will ensure pharmacy will report the date of each ZYPREXA RELPREV dispensing to the ZYPREXA RELPREV Patient Care Program.
- For each dispensing I will ensure prescription verification (includes patient eligibility check and recording the dispense date) is completed on the date of dispensing prior to the convenience kit leaving the pharmacy.
- I understand that the ZYPREXA RELPREV Patient Care Program coordinating center may contact the pharmacy to clarify information provided or obtain information about the patient.

I agree to the registration by notifying the ZYPREXA RELPREV Patient Care Program coordinating center by fax at 1-877-772-8000 or by phone at 1-877-772-8000. If I contact Lilly, Lilly will cease to supply ZYPREXA RELPREV to the pharmacy.

Date:  
Pharmacist in Charge Signature: 

PHONE 1-877-772-8000    FAX 1-877-772-5091    www.zyprexaarelpreveprogram.com

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Registration Forms

Prior to selecting and completing a registration form listed below, please ensure you have completed the appropriate training. To complete training on-line, select the "On-line Training" link below, or to receive materials in hard copy, select the "Order Educational Materials" link below.

Prescriber Registration Form
Pharmacy Registration Form
Buy & Bill Pharmacy Service Provider Registration
Patient Registration Form
  • Patient Copy
Healthcare Facility Registration Form

Do you want to complete your registration on-line or print a registration form?
  • On-line  • Print

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Version: 1.37.0, PP-OB-000057 04/2017
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BUY AND BILL® PHARMACY SERVICE PROVIDER REGISTRATION FORM

To be enrolled in the ZYPREXA RELPREVV Patient Care Program, complete this form. Training must be completed before a pharmacy service provider may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

### PHARMACY SERVICE PROVIDER INFORMATION
- **Enrollment**
- **Reenrollment**

#### Facility Name:

#### DEA Number:

#### Please specify description of Pharmacy:
- [ ] Community / Retail
- [ ] Specialty Pharmacy
- [ ] Hospital or Institution
- [ ] Other

#### Address Line 1:

#### Address Line 2:

#### City: ___________  State: ___________  Zip: ___________

#### Primary Phone: (___)______  Secondary Phone: (___)______

#### Fax: (___)______

### SHIP TO INFORMATION

#### Ship To Address (if the same as above check here) [ ]

#### Ship To Contact Name:

#### Address Line 1:

#### Address Line 2:

#### City: ___________  State: ___________  Zip: ___________
BUY AND BILL PHARMACY SERVICE PROVIDER REGISTRATION FORM

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip:</th>
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<tbody>
<tr>
<td>Primary Phone: ( ) - ___</td>
<td>Secondary Phone: ( ) - ___</td>
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<td>Fax: ( ) - ___</td>
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ADMINISTRATOR INFORMATION

<table>
<thead>
<tr>
<th>First Name:</th>
<th>MI:</th>
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<td>Preferred Method of Communication: ○ Email ○ Fax</td>
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<td>Email:</td>
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<td>Phone: ( ) - ___</td>
<td>Fax: ( ) - ___</td>
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</tbody>
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PHARMACY SERVICE PROVIDER AGREEMENT

By signing below, I acknowledge that:

- I have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.
- I understand that all appropriate pharmacy staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.
- I will ensure that all appropriate pharmacy staff understand that ZYPREXA RELPREVV can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.
- I will ensure that pharmacy staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to dispensing each prescription/refill by accessing the system.
- I will ensure that pharmacy staff will not dispense ZYPREXA RELPREVV directly to patients.
- I will ensure pharmacy staff report the date of each ZYPREXA RELPREVV dispensing to the ZYPREXA RELPREVV Patient Care Program.
- For each dispense I will ensure prescription verification (includes patient eligibility check and recording the dispense date) is completed on the date of dispense, prior to the convenience kit leaving the pharmacy.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the pharmacy to clarify information provided or to obtain information about the patient.
I have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.

☐ I will ensure that all appropriate pharmacy staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.

☐ I will ensure that all appropriate pharmacy staff understand that ZYPREXA RELPREVV can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.

☐ I will ensure that pharmacy staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to dispensing each prescription/refill by accessing the system.

☐ I will ensure that pharmacy staff will not dispense ZYPREXA RELPREVV directly to patients.

☐ I will ensure pharmacy staff report the date of each ZYPREXA RELPREVV dispensing to the ZYPREXA RELPREVV Patient Care Program.

☐ For each dispense I will ensure prescription verification (includes patient eligibility check and recording the dispense date) is completed on the date of dispense, prior to the convenience kit leaving the pharmacy.

☐ I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the pharmacy to clarify information provided or to obtain information about the patient.

I may cancel this registration by notifying the ZYPREXA RELPREVV Patient Care Program Coordinating Center by fax at 1-877-772-9391® or by phone at 1-877-772-9390®. If I cancel, Lilly will cease to supply ZYPREXA RELPREVV to the facility.

☐ I, attest that I am the Administrator, and understand that by clicking submit the information provided on this form is true and accurate.

Confirm DEA #: ____________

*Buy & Bill Pharmacy Service Provider - a licensed healthcare provider that purchases pharmaceuticals through a licensed distributor for its own use in the treatment of a patient and then includes the cost of the pharmaceutical in its billing of patients and third-party payers.
Prior to selecting and completing a registration form listed below, please ensure you have completed the appropriate training. To complete training on-line, select the "On-line Training" link below, or to receive materials in hard copy, select the "Order Educational Materials" link below.

**Prescriber Registration Form**

**Pharmacy Registration Form**

**Buy & Bill Pharmacy Service Provider Registration**

**Patient Registration Form**
- **Patient Copy**

**Healthcare Facility Registration Form**
The ZYPREXA RELPREVIV Patient Care Program will collect and use your information in the following ways:

- Your doctor will provide dose, date, and time of each injection, and other medical information to the ZYPREXA RELPREVIV Patient Care Program.
- Your information will be stored in the ZYPREXA RELPREVIV Patient Care Program computer system.
- The information will be used to help Lilly learn more about the safety of ZYPREXA RELPREVIV.
- Information from all patients in the ZYPREXA RELPREVIV Patient Care Program will be reviewed and may be combined with information from clinical studies.
- This combined information will not be able to identify you or any other patient. This combined information may be shared with:
  - Regulatory agencies,
  - doctors at other institutions,
  - the committee overseeing the ZYPREXA RELPREVIV Patient Care Program, and/or
  - publications or as part of scientific discussions.

Also, by signing this form you agree to the following:

- I understand that I must enroll in the ZYPREXA RELPREVIV Patient Care Program registry to get ZYPREXA RELPREVIV.
- I agree to have my information entered in the ZYPREXA RELPREVIV Patient Care Program registry.
- My doctor has explained the risks and benefits of treatment with ZYPREXA RELPREVIV.
- I have received a copy of the Medication Guide.
- I understand that I will be observed at the clinic for 3 hours after each injection.
- Someone must go with me to the clinic when I leave the clinic.
- I understand that I cannot drive or use heavy machinery for the rest of the day on which I get an injection.
- I agree to seek medical care right away if I have a reaction such as excessive sleepiness, dizziness, confusion, difficulty talking, difficulty walking, muscle stiffness or shaking, weakness, tremors, agitation, anxiety, increase in blood pressure or changes.
- I agree to contact my doctor if I have a reaction to ZYPREXA RELPREVIV.
- I may be asked to complete occasional surveys about my understanding of the risks and benefits of treatment with ZYPREXA RELPREVIV.
- I or my family have discussed any questions or concerns about my treatment with ZYPREXA RELPREVIV with my doctor.

You may stop participating in the ZYPREXA RELPREVIV Patient Care Program at any time by telling your doctor. If you stop participating, you will no longer be able to receive the drug. Your doctor will no longer provide any of your information to the ZYPREXA RELPREVIV Patient Care Program except to answer safety questions. The ZYPREXA RELPREVIV Patient Care Program will not use information that was collected before you stopped participating. You will be provided a copy of this form.

Signature

Printed Name of Patient

Date: [ ] [ ] [ ]

Reference ID: 4417451
Registration Forms

Prior to selecting and completing a registration form listed below, please ensure you have completed the appropriate training. To complete training on-line, select the "On-line Training" link below, or to receive materials in hard copy, select the "Order Educational Materials" link below.

Prescriber Registration Form

Pharmacy Registration Form

Buy & Bill Pharmacy Service Provider Registration

Patient Registration Form

* Patient Copy

Healthcare Facility Registration Form
information from clinical studies

- This combined information will not be able to identify you or any other patient. This combined information may be shared with:
  - regulatory agencies,
  - doctors at other institutions,
  - the committee overseeing the ZYPREXA RELPREVX Patient Care Program, and/or
  - publications or as part of scientific discussions.

Also, by signing this form you agree to the following:

- I understand that I must enrol in the ZYPREXA RELPREVX Patient Care Program registry to get ZYPREXA RELPREVX.
- I agree to have my information entered in the ZYPREXA RELPREVX Patient Care Program registry.
- My doctor has explained the risks and benefits of treatment with ZYPREXA RELPREVX.
- I have received a copy of the Medication Guide.
- I understand that I will be observed at the clinic for 3 hours after each injection.
- Someone must go with me to my destination when I leave the clinic.
- I understand that I can not drive or use heavy machinery for the rest of the day on which I get an injection.
- I agree to seek medical care right away if I have a reaction such as excessive weakness, dizziness, confusion, difficulty speaking, difficulty walking, muscle stiffness or shaking, weakness, irritability, aggression, anxiety, increase in blood pressure or convulsions.
- I agree to contact my doctor if I have a reaction to ZYPREXA RELPREVX.
- I may be asked to complete occasional surveys about my understanding of the risks and benefits of treatment with ZYPREXA RELPREVX.
- I or my caregiver have discussed any questions or concerns about my treatment with ZYPREXA RELPREVX with my doctor.

You may stop participating in the ZYPREXA RELPREVX Patient Care Program at any time by telling your doctor. If you stop participating, you will no longer be able to receive the drug. Your doctor will no longer provide any of your information to the ZYPREXA RELPREVX Patient Care Program except to answer safety questions. The ZYPREXA RELPREVX Patient Care Program will still use information that was collected before you stopped participating. You will be provided a copy of this form.
Registration Forms

Prior to selecting and completing a registration form listed below, please ensure you have completed the appropriate training. To complete training on-line, select the "On-line Training" link below, or to receive materials in hard copy, select the "Order Educational Materials" link below.

Prescriber Registration Form
Pharmacy Registration Form
Buy & Bill Pharmacy Service Provider Registration
Patient Registration Form
  * Patient Copy
Healthcare Facility Registration Form

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVIV, including Boxed Warnings.

This site is intended for U.S. residents age 18 and over.
For more information about ZYPREXA RELPREVIV, contact your doctor or other healthcare professional.
# ZYPREXA RELPREVV Patient Care Program

## Healthcare Facility Registration Form

To be enrolled in the ZYPREXA RELPREVV Patient Care Program, complete this form. Training must be completed before a healthcare facility may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

### Healthcare Facility Information

- **Facility Name:** [Enter Name]
- **Address:** [Enter Address]
- **City:** [Enter City]  **State:** [Enter State]  **Zip:** [Enter Zip]
- **Phone:** ( ) -  **Fax:** ( ) -

### Authorized Healthcare Facility Representative Information

- **First Name:** [Enter Name]  **MI:** [Enter MI]  **Last Name:** [Enter Last Name]
- **Position/Title:** [Enter Title]
- **Phone:** ( ) -  **Fax:** ( ) -
- **Email:** [Enter Email]

**Preferred Method of Communication:**  ○ Email  ○ Fax

You may identify Delegate(s) to enter the necessary patient data into the Patient Care Program system.

- **Delegate First Name:** [Enter Name]  **MI:** [Enter MI]  **Last Name:** [Enter Last Name]
- **Facility Name:** [Enter Name]
As the authorized representative for this facility, I attest that:

- I have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure;
- I will ensure that all appropriate staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure as well as the following Training Materials:
  - ZYPREXA RELPREVV Healthcare Professional Training
  - ZYPREXA RELPREVV Reconstitution and Administration Training
- I will ensure that all appropriate staff understand that ZYPREXA RELPREVV can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection;
- I will ensure the health care setting has systems, protocols, or other measures to ensure that ZYPREXA RELPREVV is only administered to patients enrolled in the program and that patients are continuously monitored for at least 3 hours post-injection for suspected PDSS;
- I will ensure that appropriate staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to each injection, by accessing the system;
- I will ensure that the Medication Guide is provided to the patient prior to each injection;
- I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours;
- I will ensure that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVV Patient Care Program.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the health care setting to clarify information provided or to obtain information about the patient.

I confirm that the information above is correct.

I understand that this information will be used to document healthcare facilities that are eligible to administer ZYPREXA RELPREVV.

I also understand that this information may be shared with government agencies.

I understand that Lilly will regularly evaluate ZYPREXA RELPREVV Patient Care Program compliance to ensure that program objectives are met. Lilly reserves the right to terminate a healthcare facility’s enrollment at any time based upon non-compliance or to take other appropriate measures to assure that the ZYPREXA RELPREVV Patient Care Program objectives are met.

I may cancel this healthcare facility registration in the future by notifying Lilly in writing and submitting the notification by fax to 1-877-772-9391® or by calling...
HEALTHCARE FACILITY REGISTRATION FORM

- I will ensure that appropriate staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to each injection, by accessing the system;
- I will ensure that the Medication Guide is provided to the patient prior to each injection;
- I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours;
- I will ensure that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVV Patient Care Program.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the health care setting to clarify information provided or to obtain information about the patient.

I confirm that the information above is correct.

I understand that this information will be used to document healthcare facilities that are eligible to administer ZYPREXA RELPREVV.

I also understand that this information may be shared with government agencies.

I understand that Lilly will regularly evaluate ZYPREXA RELPREVV Patient Care Program compliance to ensure that program objectives are met. Lilly reserves the right to terminate a healthcare facility's enrollment at any time based upon non-compliance or to take other appropriate measures to assure that the ZYPREXA RELPREVV Patient Care Program objectives are met.

I may cancel this healthcare facility registration in the future by notifying Lilly in writing and submitting the notification by fax to 1-877-772-9391 or by calling 1-877-772-9399. If I revoke this facility's registration, the facility will no longer be eligible to administer ZYPREXA RELPREVV to patients.

☐ I, attest that I am the Healthcare Facility Representative, and understand that by clicking submit the information provided on this form is true and accurate.

Confirm Facility Phone Number:
HEALTHCARE FACILITY REGISTRATION FORM

To be enrolled in the ZYPREXA Relprevv Patient Care Program, complete and fax the form to 1-877-772-4391. Training must be completed before a healthcare facility may be enrolled in the ZYPREXA Relprevv Patient Care Program.

HEALTHCARE FACILITY INFORMATION

☑ Enrolled
☐ Re-enrollment
Healthcare Facility Name: ____________________________
Please specify location of Healthcare Facilities: ☐ Prescriber Office ☐ Clinic/Outpatient Facility ☐ Hospital ☐ Other
Address: __________________________________________
City: _______ State: _______ Zip: _______
Phone: __________________________
Fax: __________________________

AUTHORIZED HEALTHCARE FACILITY REPRESENTATIVE INFORMATION

First Name: ______________________ Last Name: ______________________
Position: ______________________
Phone: ______________________ Fax: ______________________
Email: ______________________
Preferred Method of Communication: ☐ Email ☐ Fax ☐ Phone

You may identify Delegates to enter the necessary patient data into the Patient Care Program system.

<table>
<thead>
<tr>
<th>Delegate First Name</th>
<th>M: _______ Last Name: ______________________</th>
</tr>
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<tbody>
<tr>
<td>Facility Name:</td>
<td>______________________</td>
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<td>Facility Name:</td>
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</tr>
<tr>
<td></td>
<td>(different from above)</td>
</tr>
</tbody>
</table>
I will ensure that all appropriate staff are trained and have read and understand the ZYPREXA RELPREVX Patient Care Program Instructions Brochure as well as the following Training Materials:

- ZYPREXA RELPREVX Healthcare Professional Training
- ZYPREXA RELPREVX Reconstitution and Administration Training

I will ensure that all appropriate staff understand that ZYPREXA RELPREVX can only be dispensed for use in certain health care settings (e.g., hospital, clinic) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection;

I will ensure the health care setting has systems, protocols, or other measures to ensure that ZYPREXA RELPREVX is only administered to patients enrolled in the program and that patients are continuously monitored for at least 3 hours post-injection for suspected PDSI;

I will ensure that appropriate staff will verify that the patient is enrolled in the ZYPREXA RELPREVX Patient Care Program registry prior to each injection, by accessing the system;

I will ensure that the Medication Guide is provided to the patient or the patient’s legal guardian prior to each injection;

I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours;

I will ensure that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVX Patient Care Program;

I understand that the ZYPREXA RELPREVX Patient Care Program Coordinating Center may contact the healthcare setting to clarify information provided or to obtain information about the patient.

I confirm that the information above is correct.

I understand that this information will be used to document healthcare facilities that are eligible to administer ZYPREXA RELPREVX.

I also understand that this information may be shared with government agencies.

I understand that Lilly will regularly evaluate ZYPREXA RELPREVX Patient Care Program compliance to ensure that program objectives are met. Lilly reserves the right to terminate a healthcare facility’s enrollment at any time based upon non-compliance or to take other appropriate measures to assure that the ZYPREXA RELPREVX Patient Care Program objectives are met.

I may cancel this healthcare facility registration in the future by notifying Lilly in writing and submitting the notification by fax to 1-877-772-4950 or by calling 1-877-772-4950. If I revoke this facility’s registration, the facility will no longer be eligible to administer ZYPREXA RELPREVX to patients.
I confirm that the information above is correct.

I understand that this information will be used to document healthcare facilities that are eligible to administer ZYPREXA RELPREV.

I also understand that this information may be shared with government agencies.

I understand that Lilly will regularly evaluate ZYPREXA RELPREV Patient Care Program compliance to ensure that program objectives are met. Lilly reserves the right to terminate a healthcare facility's enrollment at any time based upon non-compliance or to take other appropriate measures to assure that the ZYPREXA RELPREV Patient Care Program objectives are met.

I may cancel the healthcare facility registration in the future by notifying Lilly in writing and submitting the notification by fax to 1-877-773-0591 or by calling 1-877-773-0590. If I revoke this facility's registration, the facility will no longer be eligible to administer ZYPREXA RELPREV to patients.

Authorized Healthcare Facility Representative Signature

Authorized Healthcare Facility Representative Name (print) ______________________  Title ______________________

Please fax completed form to the ZYPREXA RELPREV Patient Care Program at 1-877-773-0591.
Order Educational Materials

To order, please complete the information below and click submit.

Requestor Information
First Name: ___________ MI: __ Last Name: ___________
Address Line 1: ___________________________________________
Address Line 2: ___________________________________________
City: ___________ State: __ Zip: ___________
Phone: (______) - ___ Alternate Phone: (______) - ___
Fax: (______) - ___ Email: ___________________________

Please indicate the number of items requested in the blanks below.

Training Materials Kit for Prescriber* and Healthcare Facility

☐ Kit includes:
  • ZYPREXA RELPREVV Patient Care Program Instructions Brochure
  • Reconstitution & Administration Poster & Training Video (DVD)
  • Healthcare Professional Training Recorded Presentation (DVD) with Participant Guide
  • PDDS Case Study Video (DVD)
  • Medication Guide
  • Prescribing Information

*Note: Patient Materials will automatically ship to a prescriber after prescriber registration is complete.
"Note: Patient Materials will automatically ship to a prescriber after prescriber registration is complete.

Training Material for Pharmacy Service Providers
(traditional pharmacy operation or buy & bill prescriber)

☐ ZYPREXA RELPREV LV Patient Care Program Instructions Brochure

Training Materials Available as Individual Items

☐ ZYPREXA RELPREV LV Patient Care Program Instructions Brochure
☐ Reconstitution & Administration Poster
☐ Reconstitution & Administration Training Video (DVD)
☐ Healthcare Professional Training Recorded Presentation (DVD) with participant guide
☐ PDSS Case Study Video (DVD)

Patient Materials

☐ 10 Wristbands
☐ 10 ID cards

Forms Available as Individual Items

☐ Single Patient Injection Form - tear-off pad of forms (25 forms/pad)
☐ Multiple Patient Injection Form - tear-off pad of forms (25 forms/pad)
☐ PDSS Form - 3 forms/pack
☐ Patient Registration Form - 5 patient forms/pack

You may also contact your Lilly sales representative to request materials and resources.

I understand that any personal information provided on this form will be used to provide educational materials only. For further privacy information please see the Privacy Policy.

Submit
Prescribing Information

ZYPREXA RELPREVIV Patient Care Program

Prescribing Information

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVIV, including Boxed Warnings.

This site is intended for U.S. residents age 18 and over.
For more information about ZYPREXA RELPREVIV, contact your doctor or other healthcare professional.

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VERSION: 1.37.0, PP-QD-USL-0057 04/2017
Site hosted by United BioSource Corporation
Medication Guide
ZYPREXA RELPREV™ (by PREX-a REL-prdv)
(dolazine)

For Extended Release Injectable Suspension

Read the Medication Guide that comes with ZYPREXA RELPREV™ before you start taking it and each time before you get an injection. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment. Talk with your doctor if there is something you do not understand or you want to learn more about ZYPREXA RELPREV™.

What is the most important information I should know about ZYPREXA RELPREV™?

Before you receive ZYPREXA RELPREV™ treatment, you must:

1. understand the risks and benefits of ZYPREXA RELPREV™ treatment.
2. talk to you about the risks and benefits of ZYPREXA RELPREV™ treatment.

You must agree to the rules of the ZYPREXA RELPREV™ Patient Care Program before you register.

ZYPREXA RELPREV™ may cause serious side effects, including:

1. Post-injection Delirium Sedation Syndrome (PDSS).
2. Increased risk of death in elderly people who are confused, have memory loss and have had contact with realities (dementia-related psychoses).
3. High blood sugar (hyperglycemia).
4. High fat levels in your blood (increased cholesterol and triglycerides), especially in teenagers age 10 to 17.
5. Weight gain, especially in teenagers age 10 to 17.

These serious side effects are described below.

1. Post-injection Delirium Sedation Syndrome (PDSS).

PDSS is a serious problem that can happen after you get a ZYPREXA RELPREV™ injection if the medicine gets in your blood too fast. This problem usually happens within 3 hours after you receive ZYPREXA RELPREV™. If you have some of the following symptoms:

- feel more talkative or excited
- feel confused or disoriented
- trouble talking or walking
- muscle stiffness or shaking
- feel weak
- feel anxious or nervous

Contact your doctor after you receive ZYPREXA RELPREV™.

If you have any other questions, please speak to your doctor.
Eli Lilly and Company ("Lilly", "we", "us" or "our") respects the privacy of visitors to our websites, and as a result, we have developed this Website Privacy Statement. United BioSource Corporation ("UBC") has been contracted to collect and analyze data on behalf of Lilly for the ZYPREXA RELPREVIV patient care program.

Scope

This Website Privacy Statement is provided by Lilly to all visitors ("you" or "your") who use the publicly available pages of the ZYPREXA RELPREVIV Patient Care Program Website located at https://www.zyprexa-relpreviv.com/ (the "Site") and Authorized Users of the Patient Care Program Website. "Authorized Users" are eligible Prescribers, Healthcare Facilities, and Pharmacy Service Providers. "Prescribers" include physicians, physician's assistants, nurse practitioners, and pharmacists. "Healthcare Facility" means a healthcare facility administering and/or monitoring injections of ZYPREXA RELPREVIV. "Pharmacy Service Provider" means any retail pharmacy, hospital pharmacy, physician, or properly licensed healthcare facility that can order for and deliver ZYPREXA RELPREVIV to a healthcare professional in accordance with their agreement to implement all relevant requirements of the ZYPREXA RELPREVIV Patient Care Program. The "Patient Care Program Website" is an Authorized User-only portal available through the Site which enables Authorized Users to prescribe ZYPREXA RELPREVIV.

CONSENT TO PROCESSING IN THE UNITED STATES AND ELSEWHERE: This site is owned and operated by Lilly in the United States, but the information you provide may be accessible to our affiliates, vendors and suppliers in other countries. If you are visiting this site from a country other than the United States, information collected from you on this site will be transferred outside of your country. The level of legal protection for Personal Information is not the same in all countries; however, we will take reasonable efforts and security measures as described in this Privacy Statement in an effort to keep your information secure.

PROCESSING OF PERSONAL INFORMATION ORIGINATING IN THE EU/EEA AND SWITZERLAND: In addition to its internal global privacy policies, Lilly and its affiliates in the U.S. adhere to the U.S.-EU Privacy Shield Framework and the U.S.-Swiss Safe Harbor Framework as set forth by the U.S. Department of Commerce regarding the collection, use, and retention of Personal Information from the European Union (EU), European Economic Area (EEA) and Switzerland. Lilly may share your information collected on this site with its affiliates in the U.S. If you are a resident of an EU or EEA member country or Switzerland, see the Lilly Privacy Shield and Safe Harbor Notice available at https://www.lilly.com/privacy.asp for more information about how Lilly and its affiliates in the U.S. process your information.

By using this site, you consent to the collection, storage and processing of your information in the United
By using this site, you consent to the collection, storage and processing of your information in the United States and in any country to which we may transfer your information in the course of our business operations.

**Information We Collect**

**Information Routinely Collected by Our Website Technology**
When you visit the Site, and during your interactions with the Site, we may collect Non-Personal Information from you. "Non-Personal Information" means a data element or collection of data elements that by itself cannot ordinarily be associated with a specific individual. Non-Personal Information includes by way of example but not limitation, the Internet browser or computer operating system you are using, your navigation of the Site including the pages of the Site that you access, the amount of time spent on various portions of the Site, the length and dates of your visits to the Site, and certain Site data captured through your interactions with the Site and other sites. Non-Personal Information may include information provided by you through the Site or otherwise (e.g., through a third-party site) that is not Personal Information or Health Information. Certain Non-Personal Information may be collected on an aggregated, anonymous basis through web server logs, cookies, ad servers, tracking pixels, web beacons, and similar Internet tracking devices (collectively "Tracking Mechanisms"). Web servers automatically collect Non-Personal Information, with your IP address, when you request pages of the Site or other sites. Based on certain interactions with the Site, third-party sites, mailings, other communications with us, and/or our system configurations, certain Non-Personal Information may be associated with your Personal Information such that your Non-Personal Information is identifiable with you.

**Information You Voluntarily Provide**
You may visit most areas of this website without providing directly identifiable Personal Information or revealing your identity. However, in some cases you may choose to voluntarily provide Personal Information via this website in order to register for, or request, additional information or services, including obtaining access to the Patient care program website. In such cases, we will collect information that can identify you, such as your name, address, telephone number, email address, and other similar information ("Personal Information").

**Registration**. Registration is optional; however, Authorized Users are provided access to the Patient Care Program Website and its information and online services not provided on the public website, as well as the ability to login to the Patient Care Program Website when revisiting the Site. The Personal Information you disclose to us during registration and in connection with the Patient Care Program Website is provided strictly on a voluntary basis. We may also collect Non-Personal Information during the registration process as described above. You may register on the Patient Care Program Website by filling out a form and submit it to us online or otherwise. You will need to provide certain Personal Information including first name, last name, and/or email address to register.

The type of access and services offered through the Patient Care Program Website may depend on whether you have registered as a Prescriber, a Healthcare Facility, or a Pharmacy Service Provider.

When you become an Authorized User, you may be asked to provide us with the Personal Information and/or Health Information of one or more patients with their consent, on whose behalf you are assisting in their care by a Healthcare Facility or a Pharmacy Service Provider, or patients that you are treating. After you login to the Patient Care Program website, you may be able to view certain Personal Information and Health Information of your patients, and use other services the Patient Care Program Website may offer. The term "Health Information" means any information, in any form, related to the past, present, or future health or medical status, condition, or treatment of a person, including, by way of example, but not limitation, names of doctors, health conditions, medications, and/or prescription information and history.

**How We Use Your Information**
We may also use your Personal Information to contact you and/or provide you with general health information (like information on certain health conditions) as well as information on our products and services. We may enhance or merge your information with other data we may have about you as well as data obtained from third parties for the same purposes. Web Beacons: Our websites may use Web Beacons (sometimes called single-pixel GIFS) to generate web log information. Web log, IP Address and other Information routinely collected by our web servers in connection with your visit to this website will be used to better understand your
collected by our webserver in connection with your visit to this website will be used to better understand your needs and general user traffic patterns, and to improve our websites and services. We may enhance or merge this information with other data we may have about you as well as with data obtained from third parties for the same purposes. We also may use your IP address to personalize content provided on the website. We may retain IP addresses, and we may retain them together with your personal information.

Information routinely collected may also be stored in databases owned and maintained by Lilly or its agents, contractors, and business partners. Lilly retains their respective rights to these databases and the information contained in them.

Cookies. Our webserver can detect whether you have Cookies on your computer. It is possible that a Cookie may contain information that could be deemed identifiable. We may use the data we obtain through the use of cookies to customize your site experience by anticipating the information and services that may be of interest to you. We also analyze the information collected with cookie technology to help us improve the functioning of our site by monitoring traffic in popular areas and to modify the services and information we provide to meet customer demand. We may link the clickstream data available to us through the use of cookies to Personal Information that you may choose to provide elsewhere on our websites. We use the information we collect through the use of cookies for our business purposes, including operation of our site, as well as research and product analyses to help us better market our products. Most web browsers automatically accept Cookies but allow you to modify your browser setting to block them. If you reject Cookies, however, functionality of the site may be limited, and you may not be able to take advantage of many of the site's features. There are different methods for viewing and deleting cookies set on your machine, depending on the browser you are using. We recommend you visit the website of your web browser, where you should be able to find this information, or you can visit a site such as http://www.aboutcookies.org/default.asp. Some mobile devices store cookies not only in areas connected to the web browsers but also in an app-specific area, so you may have to check your app settings options to determine how to manage or delete cookies stored in these other areas.

Third-Party Cookies and Advertising. We may partner with third party ad networks to manage our advertising on other sites. Our ad network partners use cookies and Web beacons to collect non-personally identifiable information about your activities on this and other websites to provide you targeted advertising based upon your interests. If you would like to opt-out of, or manage, cookies used for targeted advertising, you may do so by following the options provided by the Network Advertising Initiative at http://www.networkadvertising.org/choices and the Digital Advertising Alliance at: http://www.aboutads.info/choices/. Please note that opting out of receiving targeted ads will not prevent you from being served advertisements generally.

Digital Analytics. We may analyze Non-Personal Information in the aggregate to study outcomes, costs, and provider profiles. These studies may generate Aggregate Data (described below) which we may utilize for a variety of purposes.

We may perform statistical analyses of the traffic patterns, site usage, and behaviors associated with the Site. We may use these analyses to generate Aggregate Data from the original Non-Personal Information. We may combine, separate, aggregate, or otherwise parse and process Non-Personal Information. The parsing and processing of such information may generate Aggregate Data. ‘Aggregate Data’ is summary level data, such as the number of web visitors in a specific geographic area. Aggregate Data does not contain information that can be used to identify or contact you, such as your name, address, telephone number or e-mail address, and does not reflect the original form of the Non-Personal Information collected from you.

Analytics. UBE may use certain in-house or third-party functionality to analyze your communications with us and interactions with the Site. The analysis enables us to monitor the services that we provide so that we can improve the services provided to you. These third parties will be required to protect any Personal Information in a manner consistent with this Privacy Statement. Other analysis capabilities are reflected in the description of Non-Personal Information.

Sharing Your Information
We may share the information we collect through this website with our employees, agents, contractors or partners in connection with services that these individuals or entities perform for or with us. These agents, contractors or partners are restricted from using this data in any way other than to perform these services.
contractors or partners are restricted from using this data in any way other than to perform these services. Lilly expects its employees and partners to maintain the trust placed in us by those who provide us with information by using reasonable administrative, technical and physical safeguards. Lilly and UBC reserve the right to share information to respond to duly authorized information requests of governmental authorities or where required by law. Lilly may share certain Personal Information and Health Information collected by UBC on the site with the U.S. Food and Drug Administration. In some circumstances, such as where national, state or company security is at issue, Lilly and UBC reserve the right to share our entire database of visitors and customers, and the associated Personal Information and other data we may have with appropriate governmental authorities.

We may also provide information to a third party in connection with the sale, assignment, or other transfer of the business of this website to which the information relates, in which case we will require any such buyer to agree to treat information in accordance with this Privacy Statement.

Do Not Track
Some web browsers may transmit "do-not-track" signals to websites with which the browser communicates. Our Site does not respond to web browser "do not track" signals and similar mechanisms. However, you may control certain Tracking Mechanisms as described above.

Data Security
We are committed to protecting the privacy and security of this Site. We take reasonable technical and procedural precautions to protect the information received by us. Our Internet infrastructure is protected using industry-recognized commercial security products, including current encryption technology, and best practice procedures for maintenance of the website. In addition, our infrastructure is monitored 24 hours a day, seven days a week.

No method of transmission over the Internet or storage of data on an Internet server is 100% secure. Although we use commercially acceptable and reasonable precautions to protect your information, we do not guarantee its absolute security.

Children
This site is not intended for, or designed to attract, individuals under the age of 18. We do not knowingly collect Personal Information from any person under the age of 18.

More Information

Links to Other Websites
As a convenience to our visitors, our websites may contain links to a number of sites owned and operated by third parties that we believe may offer useful information. The policies and procedures we describe here do not apply to those sites. Lilly or UBC is not responsible for the collection or use of information at any third party sites. We suggest contacting those sites directly for information on their privacy, security, data collection, and distribution policies.

California Privacy Rights
Your Privacy Rights: California Civil Code Section 1798.83 entitles California residents who have an established business relationship with Lilly to request information regarding Lilly’s disclosure of certain Personal Information to third parties for their direct marketing purposes. To make a request for such information, you may contact us in writing to: ZYPREXA RELPREVIVE Patient Care Program Coordinating Center at 200 Pinecrest Plaza, Morgantown, WV 26505 or you may call 877-772-9399.

Changes to Our Privacy Practices
We may update this Privacy Statement from time to time. When we do update it, for your convenience, we will make the updated statement available on this page. We will always handle your Personal Information in accordance with the Privacy Statement in effect at the time it was collected. We will not make any materially different use your Personal Information unless we notify you and give you an opportunity to object.

Choices and Questions
If you voluntarily provide us with Personal Information on this website and later decide to opt-out of this decision, you may write to the ZYPREXA RELPREVIVE Patient Care Program Coordinating Center at 200 Pinecrest
Plaza, Morgantown, WV 26505 or you may call 877-772-9360.

If you are receiving commercial emails from us you may write to the address below or follow the opt-out instructions on those emails.

Please note that you may continue to receive materials while we are updating our lists. You can correct or update your Personal Information at any time by contacting the ZYPREXA RELPREVV Patient Care Program Coordinating Center. If you have any other questions or comments about this Privacy Statement please contact us by writing to: ZYPREXA RELPREVV Patient Care Program Coordinating Center at 200 Pinecrest Plaza, Morgantown, WV 26505 or you may call 877-772-9360.

Updated [09Dec2016]
ZYPREXA RELPREVV Patient Care Program

Terms Of Use

Purpose

This website has been prepared for the purpose of providing information about the ZYPREXA Relprevv Patient Care Program. This site is intended for use only by residents of the United States who are age 18 or older.

This website (this "Site") is administered by staff at United BioSource Corporation ("UBC") on behalf of its sponsor Eli Lilly and Company ("Lilly").

UBC makes information about the ZYPREXA Relprevv Patient Care Program available on this Site, subject to the following Terms of Use ("Terms"). UBC reserves the right to change these Terms at any time without notice. You agree to be bound by the most recent version of the Terms posted on this Site. These Terms represent the entire understanding between you and UBC relating to the use of this Site.

Security Notice

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Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVIV, including boxed warnings.

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