

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-173

REMS

NDA 22-173 Zyprexa® Relprevv™ (olanzapine)

For Extended Release Injectable Suspension

Eli Lilly and Company

Indianapolis, IN 46285

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Zyprexa Relprevv Patient Care Program

I. GOALS

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 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
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 prescription for Zyprexa Relprevv in accordance with 21 CFR 208.24 and by the Healthcare Provider (HCP) as described below.

Lilly will include the Medication Guide inside each Zyprexa Relprevv convenience kit which is a single unit of dispensing. The Medication Guide will also be available on the Zyprexa Relprevv Patient Care Program website.

Please see appended Medication Guide.

B. Communication Plan

In accordance with the United States (US) Federal Food, Drug, and Cosmetic Act (FDCA) 505-1(e)(3), Lilly will issue a Dear Healthcare Professional Letter to 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 will be issued by mass mailing one time at product launch.

The Dear Healthcare Professional Letter is part of the REMS and is appended.

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.

1. Healthcare providers who prescribe Zyprexa Relprevv are specially certified under 505-1(f)(3)(A).

- 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 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.
 - 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 prior to prescribing;
 - 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 non-compliant 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 healthcare 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 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 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;
 - 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 prior to each injection;
 - g) I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours;

- 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 healthcare 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;
 - 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 healthcare 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 healthcare facility;
 - v. verification that the patient was accompanied upon leaving the healthcare facility;
 - vi. any report of a PDSS event since the previous Zyprexa Relprevv injection;
 - vii. verification that the healthcare 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;
 - vii. pre-existing 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

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 FDA at 6 months and 1 year after the approval date of the NDA for Zyprexa Relprevv, and annually thereafter. 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.

[Date]

Re: Important Safety Information on ZYPREXA[®] RELPREVV[™] (olanzapine) For Extended Release Injectable Suspension and Post-Injection Delirium/Sedation Syndrome

Dear Healthcare Professional,

ZYPREXA[®] RELPREVV[™] (olanzapine) For Extended Release Injectable Suspension was approved for the treatment of schizophrenia in adults on [insert date]. ZYPREXA RELPREVV is an injectable formulation of ZYPREXA[®] (olanzapine), an atypical antipsychotic, that sustains the delivery of olanzapine for a period of up to four weeks.

Eli Lilly and Company would like to inform you of important safety information regarding ZYPREXA RELPREVV and its association with a post-injection delirium/sedation syndrome characterized primarily by signs and symptoms consistent with olanzapine overdose. The prescribing information for ZYPREXA RELPREVV (olanzapine) For Extended Release Injectable Suspension includes the following **BOXED WARNINGS**. **Post-injection delirium/sedation syndrome does not apply to any other formulation of olanzapine, including ZYPREXA IntraMuscular (olanzapine for injection).**

WARNINGS:

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 [see *Dosage and Administration (2.1)*, *Warnings and Precautions (5.1, 5.2)*, *Overdosage (10.2)*, and *Patient Counseling Information (17.2)*].

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 [see *Warnings and Precautions (5.3) and Patient Counseling Information (17.3)*].

ZYPREXA RELPREVV is available only through a restricted distribution program. ZYPREXA RELPREVV 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 RELPREVV Patient Care Program. To enroll, call 1-877-772-9390.

When prescribing ZYPREXA RELPREVV, it is important for healthcare professionals to follow all recommended conditions for safe use and to inform patients of this potential risk.

- ZYPREXA RELPREVV should only be administered by deep intramuscular gluteal injection by a healthcare professional trained in the appropriate injection technique. ZYPREXA RELPREVV 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.
- Patients should be advised about this potential risk and the need to be continuously observed for at least 3 hours following dose administration at the healthcare facility each time ZYPREXA RELPREVV is administered.
- Prior to administering the injection, the healthcare facility should confirm that someone will accompany the patient to his/her destination upon leaving the facility.
- After each injection, a healthcare professional must continuously observe the patient at the healthcare facility for at least 3 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.
- If parenteral benzodiazepines are required for patient management during an event of post-injection delirium/sedation syndrome, careful evaluation of clinical status for excessive sedation and cardiorespiratory depression is recommended.

Signs and Symptoms of Post-Injection Delirium/Sedation Syndrome: During premarketing clinical studies of ZYPREXA RELPREVV, 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. Clinical signs and symptoms included dizziness, confusion, disorientation, slurred speech, altered gait, difficulty ambulating, weakness, agitation, extrapyramidal symptoms, hypertension, convulsion, and reduced level of consciousness ranging from mild sedation to coma.

Rate of Occurrence and Timing of Post-Injection Delirium/Sedation Syndrome Events: These events occurred in <0.1% of injections and in approximately 2% of patients who received injections for up to 46 months. Time after injection to event ranged from soon after injection to greater than 3 hours after injection. The potential for onset of an event is greatest within the first hour. All of these patients 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).

Mechanism of Post-Injection Delirium/Sedation Syndrome: The exact mechanism of post-injection delirium/sedation syndrome is unknown. 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.

Please refer to the Important Safety Information and full prescribing information for ZYPREXA RELPREVV included with this letter. Should you have any questions or would like additional information or educational materials regarding this important safety information, please contact the Lilly medical department at 1-800-Lilly-Rx or your Lilly sales representative.

The medical community can further our understanding of adverse events by reporting all events to the Food and Drug Administration via the MedWatch program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, via the MedWatch website at: www.fda.gov/Safety/MedWatch, or by mail:

MEDWATCH
Food and Drug Administration
5515 Security Lane
Suite 5100, HFD-001
Rockville, MD 20852

Sincerely,

Donald Therasse, M.D.
Vice President, Global Patient Safety
Eli Lilly and Company

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



ZYprexa Relprevv™
*(olanzapine) For Extended Release
Injectable Suspension*

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).

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

ZYPREXARelprevv[™]
(olanzapine) For Extended Release
Injectable Suspension

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

Training Content

At the end of this training, you should 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

ZYPREXA RELPREVV and ZYPREXA IntraMuscular –

Although both have olanzapine as their active ingredient and both are injected intramuscularly, they are intended for different indications and different dosing schedules

Category	ZYPREXA RELPREVV	ZYPREXA IntraMuscular
Indication	Treatment of schizophrenia	Agitation associated with schizophrenia and bipolar mania in adults
Generic Name	(olanzapine) For Extended Release Injectable Suspension	olanzapine for injection
Formulation	olanzapine pamoate suspension	olanzapine solution
Injection technique	IM, gluteal only	IM
Doses	150 mg/2wk, 210 mg/2wk, 405 mg/ 4wk, 300 mg/2wk	2.5 mg, 5 mg, 7.5 mg, 10 mg
Vial cap color & package lettering	terra cotta (210 mg), olive (300 mg), or blue (405 mg)	purple
Reconstitution	with special diluent provided in kit	with sterile water for injection
Appearance of medication in syringe	opaque yellow	clear yellow

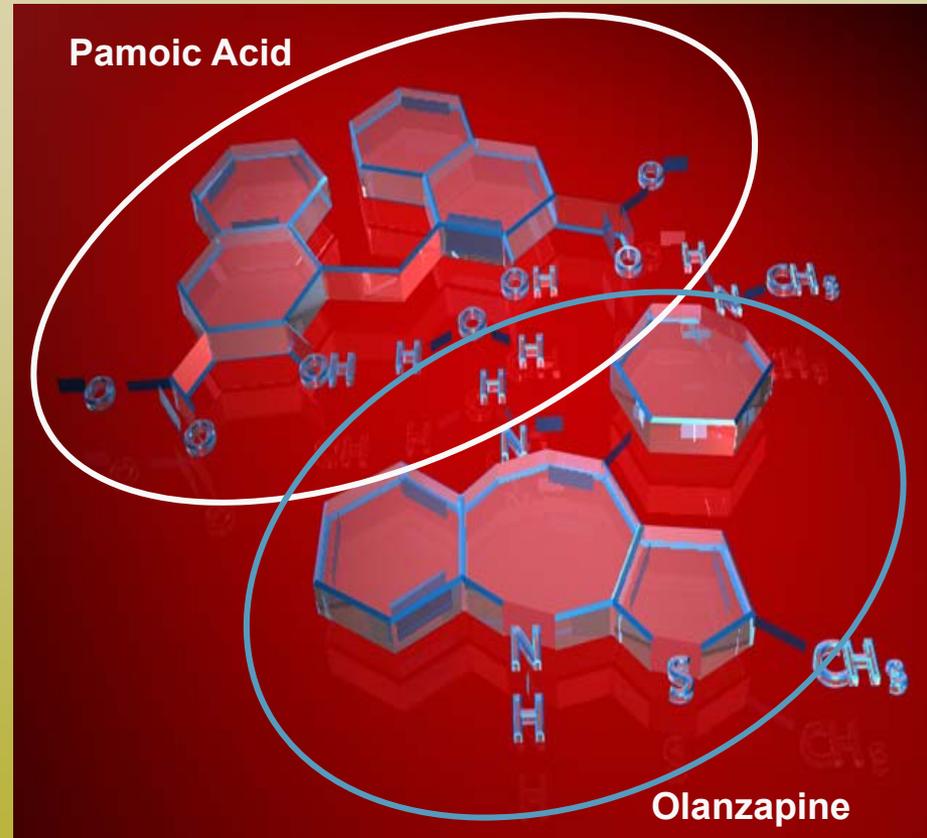
For complete safety profile, including boxed warnings, see the full Prescribing Information.

ZYPREXA RELPREVV
(olanzapine) For Extended Release
Injectable Suspension

ZYPREXA
IntraMuscular
Olanzapine for Injection

ZYPREXA RELPREVV: Formulation

- **Olanzapine pamoate salt**
 - Olanzapine plus pamoic acid
 - Crystalline
 - Insoluble in water
- **Why use pamoate salts?**
 - Decreases solubility
 - Extended delivery
 - Long action up to 4 weeks
 - No known pharmacological activity
 - Excreted unchanged
 - Used in other approved products



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

ZYPREXARelprevv[™]
(olanzapine) For Extended Release
Injectable Suspension

ZYPREXA RELPREVV: 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**



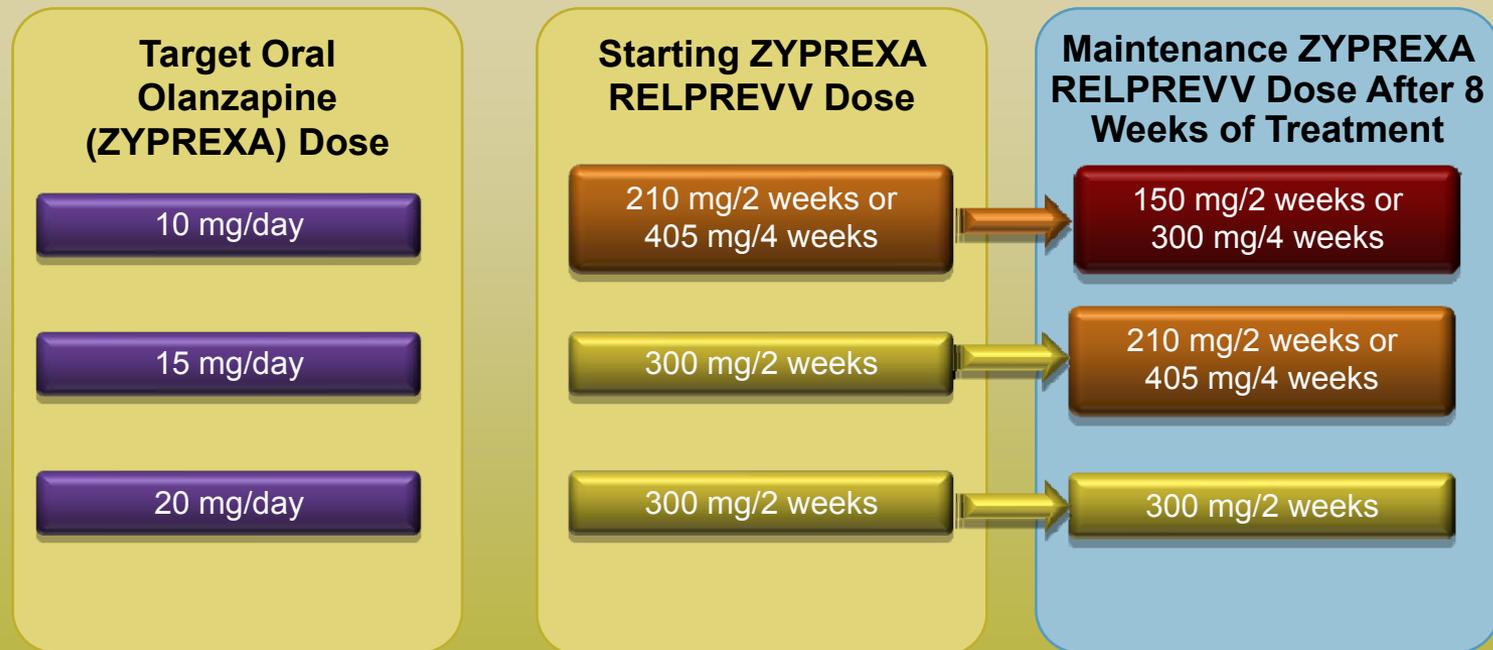
Review the ZYPREXA RELPREVV Reconstitution and Administration Training Video and the Reconstitution and Administration Poster before reconstituting the product

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

ZYPREXARelprevv[™]
(olanzapine) For Extended Release
Injectable Suspension

Dosing of ZYPREXA RELPREVV

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



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

ZYPREXA
Olanzapine

ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

Comparable Safety Profile Between ZYPREXA RELPREVV and Oral Olanzapine: 24-Week Study

Treatment-Emergent Adverse Events: Incidence >2% with ZYPREXA RELPREVV

	ZYPREXA RELPREVV (N=599) %	Oral Olanzapine (N=322) %
Patients with ≥ 1 TEAE	52.1	46.9
Weight Increased	7.2	7.5
Insomnia	7.2	4.0
Nasopharyngitis	4.3	4.3
Anxiety	4.8	2.8
Headache	3.2	4.3
Somnolence	3.8	2.8
Injection site pain	2.3	0.9
Hallucination	2.3	0.6

None of these events were statistically significantly different

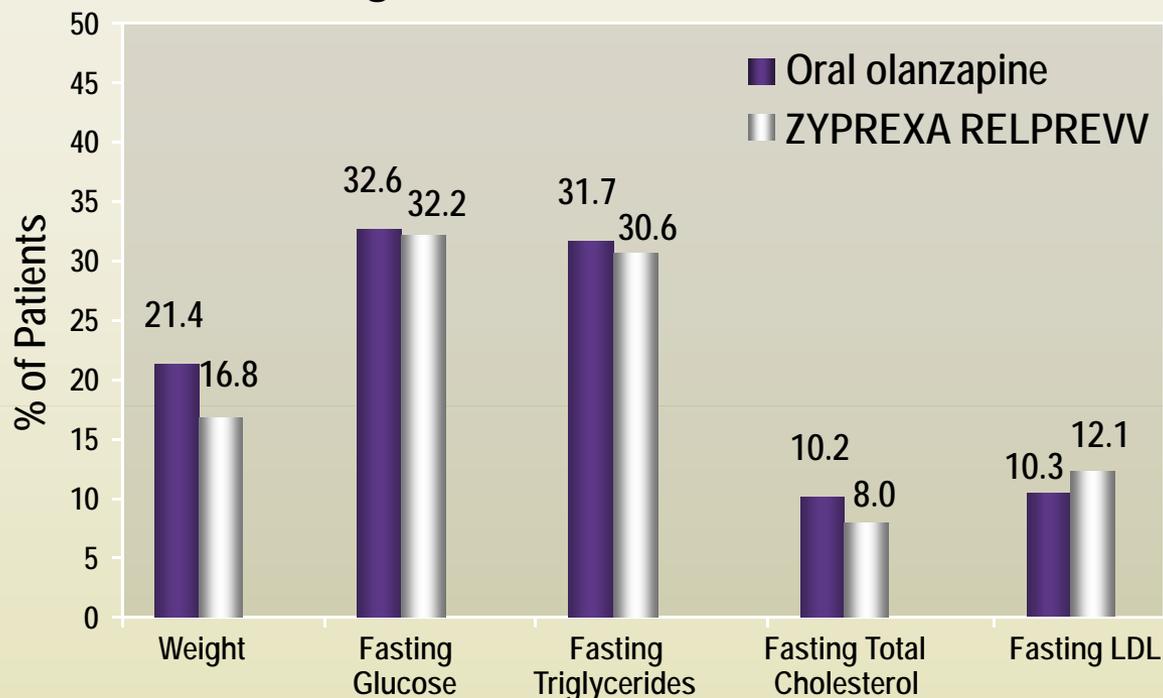
Adverse events reported with ZYPREXA RELPREVV were consistent with adverse events reported with oral olanzapine, taking into account method of administration. Data on file, Lilly Research Laboratories, ZYP20081111D

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

ZYPREXARelprevv
(olanzapine) For Extended Release
Injectable Suspension

Metabolic Changes Similar to Oral Olanzapine in the 24-Week Study

Potentially Clinically Significant Changes in Weight and Metabolic Parameters



- No significant differences between groups

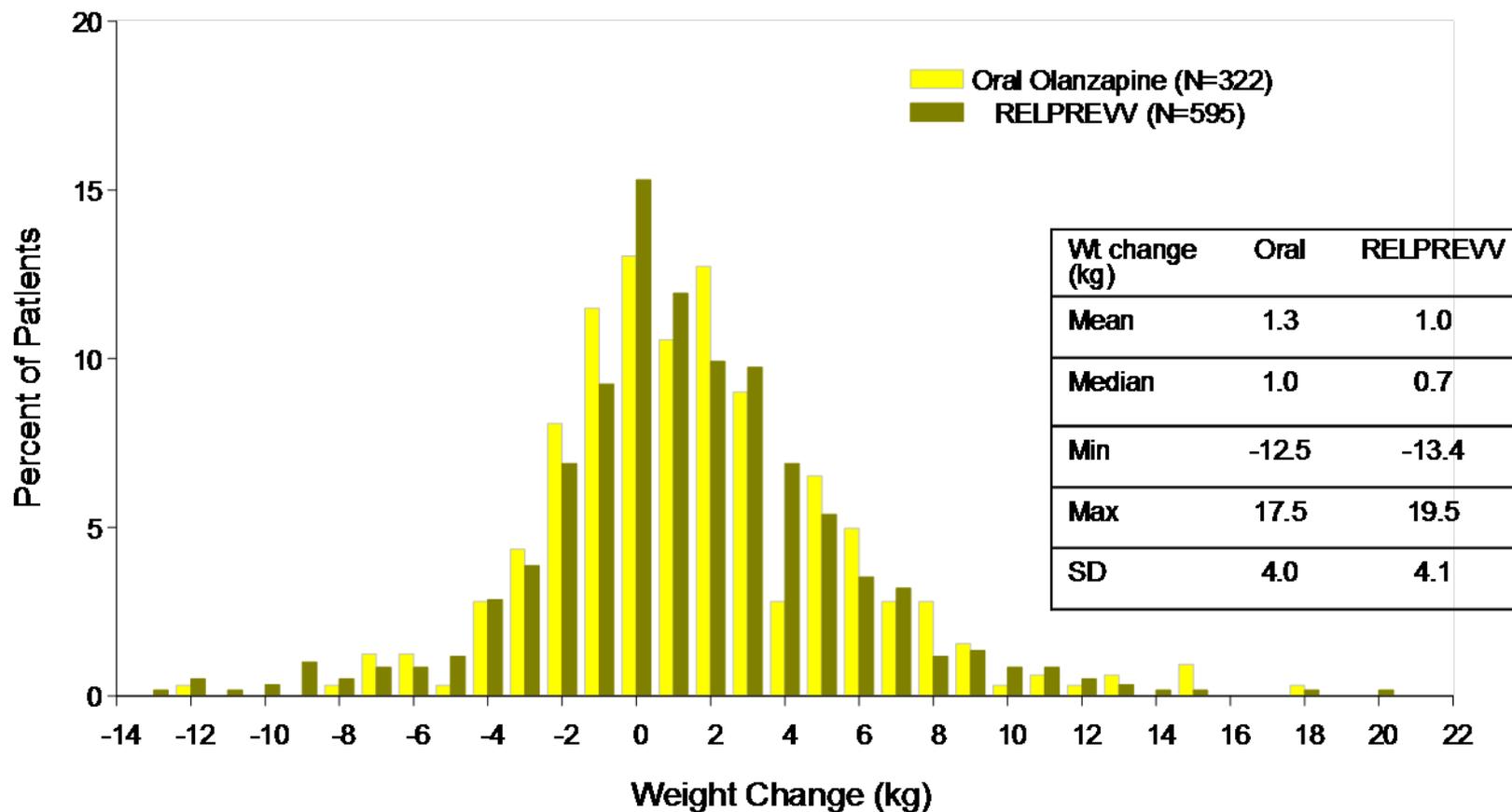
Oral olanzapine	N 322	285	265	265	253
ZYPREXA RELPREVV	N 595	481	448	448	429

Potentially clinically significant definitions: weight, $\geq 7\%$ change from baseline; fasting glucose, ≥ 10 mg/dL increase; fasting triglycerides, ≥ 50 mg/dL increase; total fasting cholesterol, ≥ 40 mg/dL increase; fasting LDL, ≥ 30 mg/dL increase.

Data on file, Lilly Research Laboratories; ZYP20081112A.

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

Similar Weight Change Between ZYPREXA RELPREVV and Oral Olanzapine Over 24 Weeks



Note that baseline is after 4-8 wks on oral olanzapine. Mean weight gain during this lead in period was 1.06 kg.

Oral = Oral olanzapine.

Data on file, Lilly Research Laboratories, ZYP20081112D

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

ZYPREXA **Relprevv**
(olanzapine) For Extended Release
Injectable Suspension

Differences by Dose with ZYPREXA RELPREVV

In a 24-week randomized, double-blind, fixed-dose study comparing 3 doses of ZYPREXA RELPREVV in patients with schizophrenia, statistically significant differences among dose groups were observed for the safety parameters below.

	Increasing ZYPREXA RELPREVV Dose 		
	150 mg/2 wk	405 mg/4 wk	300 mg/2 wk
Weight (kg) ^a	0.67	0.89	1.70*
Prolactin (μg/L) ^a	-5.61	-2.76	3.57*†
Fasting triglycerides ^b	6.5%	9.8%	24.5%*†

^a Mean change

^b Change from normal at baseline to high at any time (%)

* $P < .05$ versus 150 mg/2 wk

† $P < .05$ versus 405 mg/4 wk

Data on file, Lilly Research Laboratories, ZYP20081112B

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

ZYPREXARelprevv
(olanzapine) For Extended Release
Injectable Suspension

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

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

Post-Injection Delirium/Sedation Syndrome (PDSS) Events in Premarketing Clinical Trials*

- In premarketing ZYPREXA RELPREVV clinical trials:
 - >2000 patients have received ZYPREXA RELPREVV
 - >50,000 injections have been given
 - PDSS events occurred in 0.07% of injections (~1 event per 1400 injections), in approximately 1.7% of patients*
 - In a clinic with 60 patients given 1 injection every 2 weeks, a 0.07% incidence would suggest that the clinic would see approximately 1 PDSS event per year

A PDSS event can occur in any patient at any injection

* As of 18 June 2009, Data on file, Lilly Research Laboratories, ZYP20081112C

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

ZYPREXARelprevv
(olanzapine) For Extended Release
Injectable Suspension

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

Time of Onset of Symptoms	% of Patients*
≤1 hour	~80%
>1 to 3 hours	~ 14%
>3 hours	~ 6%

* As of 18 June 2009.
Data on file, Lilly Research
Laboratories, ZYP20090209A

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

ZYPREXA *Relprevv*
(olanzapine) For Extended Release
Injectable Suspension

Medical Status and Recovery

- **In patients experiencing Post-Injection Delirium/Sedation Syndrome Events*:**
 - No clinically significant decreases in blood pressure noted
 - No respiratory depression noted
 - Some patients experienced temporary unconsciousness (~ 15%)
 - Most patients were hospitalized for further observation and/or treatment (~ 74%)
 - Two patients were intubated prophylactically following parenteral administration of benzodiazepines (No respiratory depression noted)
 - Concomitant medications/substances have not been shown to be risk factors
- **Recovery in patients experiencing Post-Injection Delirium/Sedation Syndrome Events*:**
 - All patients have largely recovered within 72 hours
 - Approximately 70% of patients chose to continue to receive ZYPREXA RELPREVV injections after experiencing a PDSS event

* As of 18 June 2009. Data on file, Lilly Research Laboratories, ZYP20090209A

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

ZYPREXA *Relprevv*
(olanzapine) For Extended Release
Injectable Suspension

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 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

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

Safety Precautions at Every ZYPREXA RELPREVV Injection

■ 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

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

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**

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

ZYPREXA RELPREVV Patient Care Program

- **ZYPREXA RELPREVV is available only through a controlled distribution system to registered prescribers for use in registered facilities**
- **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.

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

ZYPREXARelprevv
(olanzapine) For Extended Release
Injectable Suspension

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.zyprexarelprevvprogram.com or call 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 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.

ZYPREXARelprevv
(olanzapine) For Extended Release
Injectable Suspension

Patient Registration

All patients who, in consultation with their prescribers, elect to be 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 guardian will consult with the prescriber and provide attestation for the patient

Healthcare Facility or Program Registration

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 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 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 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.

ZYPREXARelprevv[™]
(olanzapine) For Extended Release
Injectable Suspension

Pharmacy Service Provider Registration

All pharmacy service providers that intend to order and dispense ZYPREXA RELPREVV must enroll in the ZYPREXA RELPREVV 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 staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure
- Ensuring 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
- Ensuring 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
- Ensuring that pharmacy staff will not dispense ZYPREXA RELPREVV directly to patients
- Ensuring that pharmacy staff report the date of each ZYPREXA RELPREVV dispensing to the ZYPREXA RELPREVV Patient Care Program
- Understanding that the pharmacy may be contacted by the ZYPREXA RELPREVV 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.

Training Summary

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



CREATIVE STREET MEDIA GROUP

Eli Lilly and Company
Recon/Admin Olz LAI DVD VIDEO- U.S.
CS: Li08-111
DRAFT61 12.2.08 (US Draft 2-16-09)

U.S. VERSION

Title: ZYPREXA RELPREVV Reconstitution and Administration Training Video

Chapter Selections:

- Introduction
- Post-injection Delirium/Sedation Syndrome
- Step 1: Prepare Materials
- Step 2: Determine Volume
- Step 3: Reconstitute
- Step 4: Inject
- Ventrogluteal Injection
- Dorsogluteal Injection
- Recap
- Important Safety Information

#	VIDEO	AUDIO
CHAPTER 1: INTRODUCTION		
1	Text on-screen: ZYPREXA® RELPREVV™ (olanzapine) For Extended Release Injectable Suspension is an antipsychotic agent indicated for the acute and maintenance treatment of schizophrenia in adults.	Narrator: All healthcare professionals who administer this product must view this video before giving an injection of ZYPREXA RELPREVV.

Creative Street Media Group

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Television Programming ♦ Video & Audio Post Production
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	<p>All healthcare professionals who administer this product must view this video before giving an injection of ZYPREXA RELPREVV.</p> <p>For important safety Information, including boxed warnings, see the end of this program and the full prescribing information provided.</p>	
2	<p>Fade up to video of nurse (talent) talking to camera.</p> <p>Text: <u>Vial strengths</u> 210 mg, 300 mg, and 405 mg <u>Dosing schedules</u> Every 2 weeks: 150-mg, 210-mg, or 300-mg doses Every 4 weeks: 300-mg or 405-mg doses</p>	<p>Narrator: ZYPREXA RELPREVV is a long acting injectable formulation of olanzapine. It is indicated for the acute and maintenance treatment of schizophrenia in adults. The efficacy of ZYPREXA RELPREVV is consistent with the established efficacy of orally administered Zyprexa for treatment of schizophrenia in adults.</p> <p>ZYPREXA RELPREVV is available in 210-, 300-, and 405-milligram vials. It may be administered every 2 weeks in 150-mg, 210-mg, or 300-mg doses, or every 4 weeks in 300-mg or 405-mg doses.</p>
3	<p>Title: ZYPREXA RELPREVV Reconstitution and Administration Training Video</p> <ul style="list-style-type: none"> ➤ Description of Post-injection Delirium/Sedation Syndrome ➤ Demonstration of ZYPREXA RELPREVV product reconstitution ➤ Demonstration of injection technique ➤ Real-time demonstration of reconstitution and administration process 	<p>Narrator:</p> <p>The purpose of this video is to teach you how to properly reconstitute and administer ZYPREXA RELPREVV. First we will begin by explaining the Post-injection Delirium/Sedation Syndrome events that occurred with ZYPREXA RELPREVV in pre-marketing clinical trials. Then, we will demonstrate step-by-step instructions on how to properly reconstitute the product. Once it has been reconstituted, we will show you the proper administration techniques and demonstrate the entire reconstitution and administration process in real time.</p> <p>Please watch the end of this video and see accompanying full prescribing information for important safety information including boxed warnings.</p>
CHAPTER 2: POST-INJECTION DELIRIUM/SEDATION SYNDROME		
4	<p>Text on screen: POST-INJECTION DELIRIUM/ SEDATION SYNDROME</p>	<p>Narrator: During pre-marketing clinical studies, events that presented with signs and symptoms consistent with olanzapine overdose were reported in some patients</p>

	<p>(use slides, once finalized and approved.)</p> <p>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</p>	<p>following an injection of ZYPREXA RELPREVV. These events occurred in fewer than 0.1% of injections and in approximately 1.5% of patients who received injections for up to 46 months.</p> <p>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 include extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension or possible convulsion.</p> <p>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. 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.</p> <p>Patients experiencing post-injection delirium/sedation syndrome should be managed as clinically appropriate.</p> <p>Patients may be treated symptomatically.</p> <p>If a Post-injection Delirium/Sedation Syndrome event is suspected, close medical supervision and monitoring should be conducted in a facility capable of resuscitation.</p> <p>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.</p> <p>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”</p> <p>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.</p>
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<p>give the injection.</p> <p>Before patient leaves the healthcare facility:</p> <ul style="list-style-type: none"> ▪ 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 be able to obtain assistance if needed ▪ All patients should be accompanied to their next destination upon leaving the facility <p>After leaving the healthcare facility:</p> <ul style="list-style-type: none"> ▪ Patients should not drive or operate heavy machinery for remainder of day 	<p>After each ZYPREXA RELPREVV injection:</p> <ul style="list-style-type: none"> ➤ 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 <p>Before the patient leaves the healthcare facility:</p> <ul style="list-style-type: none"> ➤ 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 <p>After leaving the healthcare facility:</p> <ul style="list-style-type: none"> ➤ Patients should not drive or operate heavy machinery for the remainder of day <p>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.</p> <p>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</p> <ul style="list-style-type: none"> ➤ 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 <p>Therefore, ZYPREXA RELPREVV is intended for deep</p>
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		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. Post-injection Delirium/Sedation Syndrome can occur at any injection, so safety precautions should be observed every time the product is administered.
CHAPTER 3: STEP ONE		
5	<p>Text on-screen: Reconstitution Step 1- Prepare Materials</p> <p>Pair of hands placing gloves and alcohol wipes on counter. Hands place prescribed dose of ZYPREXA RELPREVV</p> <p>C/U of contents of kit.</p> <p>Hands open kit and arrange materials on counter.</p> <p>Put gloves on hands.</p>	<p>Narrator: Let's begin by preparing for the ZYPREXA RELPREVV injection.</p> <p>First, you will need to gather and prepare your materials.</p> <p>Obtain 1 pair of gloves, several alcohol wipes, and the prescribed dose of ZYPREXA RELPREVV.</p> <p>The medication comes packaged in a convenience kit that includes the following items: 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.</p> <p>Open the kit, remove all items, and arrange them conveniently to prepare for reconstitution.</p> <p>You will need to wear gloves when reconstituting ZYPREXA RELPREVV, as the medication can be irritating to the skin. If the medication contacts skin, flush it with water.</p>
CHAPTER 4: STEP TWO		
6	<p>Text on-screen: Step 2: Determine Reconstitution Volume C/U of table...</p> <p>Finger point towards 210mg on table...</p> <p>Text on-screen: There will be excess diluent remaining in the vial.</p>	<p>Narrator: Next you will need to determine the reconstitution volume. Please refer to the table in the full-color poster of the reconstitution and administration instructions for the proper volumes of diluent to add for each vial strength. The table is located under the section entitled "Step 2 DETERMINING THE RECONSTITUTION VOLUME.</p> <p>For example, if you are preparing a 210mg dose, you will need to add 1.3ml of diluent to the 210mg powder vial.</p> <p>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.</p>
CHAPTER 5: STEP THREE		

7	<p>Text on-screen: Step 3: Reconstitute</p> <p>Tap the vial</p> <p>Withdraw 1.3ml of diluent.</p> <p>Inject diluent into vial. While needle is still in vial, pull back on the plunger.</p> <p>Hold vial upright when removing needle.</p> <p>Engage safety syringe.</p> <p>Tap vial on hard surface. Text on screen: Tap firmly and repeatedly</p> <p>Close-up of vial, looking for clumps. Tap vial again, if clumps are seen.</p> <p>Shake vial vigorously. Close-up of suspension.</p> <p>Foam in vial. Set vial on hard surface for foam to dissipate.</p> <p>Text on-screen: Product is stable in the vial for 24 hours after reconstitution.</p>	<p>Narrator: Now you are ready to reconstitute ZYPREXA RELPREVV. The process of reconstitution and administration should take around 5 minutes to complete.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Hold the vial upright when removing the needle to prevent any loss of medication.</p> <p>Next, engage the safety needle and push the air out of the syringe.</p> <p>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.</p> <p>Check for clumps by inspecting the sides and bottom of the vial. Unsuspended powder appears as light yellow, dry clumps clinging to the vial. If clumps are visible, tap the vial again to break the clumps free.</p> <p>Shake the vial vigorously until the suspension appears smooth and consistent in color and texture.</p> <p>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.</p> <p>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</p>
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		shaken to resuspend before being withdrawn into the syringe for administration. Once drawn up into the syringe, this medication should be injected immediately.
CHAPTER 6: STEP FOUR		
8	<p>Text on-Screen: Step 4: Inject ZYPREXA RELPREVV</p> <p>Close-up of table in instructions.</p> <p>1.4ml withdrawn from vial.</p> <p>Text on-screen: There will be excess medication remaining in the vial.</p> <p>Tap the syringe.</p> <p>Engage needle safety device.</p> <p>Safety needle attached to syringe.</p>	<p>Narrator: Attach a new safety needle to the syringe.</p> <p>For all doses, the concentration of olanzapine in the suspension is 150 mg per 1 ml.</p> <p>When preparing to draw up the prescribed dose, please refer to the table in the full-color poster of the reconstitution and administration instructions for the correct injection volume. The table is located under the section entitled "Step 4 - INJECTING ZYPREXA RELPREVV."</p> <p>For a prescribed dose of 210mg, you will withdraw 1.4ml from the reconstituted vial. 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. There will be excess medication remaining in the vial.</p> <p>To ensure the full dose is given, tap the syringe with your fingers to remove all excess air bubbles.</p> <p>Once the desired dose is withdrawn, remove the needle from the vial, and engage the needle safety device.</p> <p>Attach a new safety needle to the syringe.</p>
9	<p>Text On-Screen: Do not inject the medication intravenously or subcutaneously.</p> <p>Graphic/Model showing ventrogluteal and dorsogluteal muscles.</p>	<p>Narrator:</p> <p>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. Even if accompanied, the patient may not drive to his or her destination or for the rest of the day of injection.</p> <p>Now you are ready to give the injection of ZYPREXA RELPREVV. Once the medication is drawn into the syringe, it should be injected immediately.</p> <p>First, select and prepare a site for injection. This injection can be given in the ventrogluteal or the dorsogluteal muscle. These two areas have large muscle density and</p>

		<p>are clinically appropriate sites for deep gluteal injections.</p> <p>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.</p>
CHAPTER 7: VENTROGLUTEAL INJECTION		
10	<p>Text: VENTROGLUTEAL INJECTION</p>	<p>Narrator: 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.</p> <p>Point your thumb at the groin and fingers towards the person's head. Form a "V" 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.</p> <p>Insert the needle into the 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.</p> <p>In this case, no blood is seen, so we will inject the medication with steady pressure</p> <p>After withdrawing the needle carefully from the muscle, engage the needle safety device.</p> <p>Do not massage the injection site</p> <p>Finally, after the injection, make sure to dispose of the vials, needles, and syringe appropriately.</p>
CHAPTER 8: DORSOGLUTEAL INJECTION		
11	<p>Text: DORSOGLUTEAL INJECTION</p> <p>Insert needle into correct location on model. Pull back on plunger.</p> <p>Withdraw needle from model, engage safety device. Text On-Screen: Do not massage the area after the injection.</p>	<p>Narrator: 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.</p> <p>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.</p> <p>In this case, no blood is seen, so we will inject the medication with a steady pressure.</p> <p>After withdrawing the needle carefully from the gluteal</p>

	Dispose of vials, syringe safely. Text On-Screen: Note: The vial is for single use only.	muscle, engage the needle safety device Do not massage the injection site. Finally, after the injection, make sure to dispose of the vials, needles, and syringe appropriately.
CHAPTER 9: RECAP		
12	Graphic on Screen: 1: Prepare Materials 2: Determine Reconstitution Volume 3: Reconstitute 4: Inject	Narrator: To summarize, the process of reconstituting and administering ZYPREXA RELPREVV can be broken down into four easy steps, One: Prepare Materials. Two: Determine Reconstitution Volume. Three: Reconstitute; and four, Inject.
13	Go through process of reconstitution in real-time. Provide Stop Watch to be shown on-screen.	Narrator: 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.
14	Text on Screen: Add phone number www.ZyprexaRelprevv.com website	Narrator: If you have any questions about reconstituting and administering ZYPREXA RELPREVV please contact the number on-screen or visit the following website.
CHAPTER 10: IMPORTANT SAFETY INFORMATION		
15	Text on screen: Important Safety Information for ZYPREXA RELPREVV [Scroll the approved ISI.] Refer to the package insert for ZYPREXA RELPREVV for additional information. Fade to Black	ISI information to be added after it has been approved.

Instructions to Reconstitute and Administer ZYPREXA RELPREVV



ZYPREXA *Relprevv*[™]
(olanzapine) For Extended Release
Injectable Suspension

**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



Figure 1: Contents of convenience kit.

Convenience kit includes:

(See Figure 1 on left)

- 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® safety needle
- Two 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needles with 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.

STEP 2 DETERMINING RECONSTITUTION VOLUME

Dose	Vial Strength	Diluent to Add
150 mg	210 mg	1.3 mL
210 mg	210 mg	1.3 mL
300 mg	300 mg	1.8 mL
405 mg	405 mg	2.3 mL

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



Figure 2: Tap firmly to mix.



Figure 3: Check for unsuspended powder and repeat tapping if needed.



Figure 4: Vigorously shake vial.

- Loosen the powder by lightly tapping the vial.
- 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 instruction for use).
- Pad a hard surface to cushion impact (see Figure 2). Tap the vial firmly and repeatedly on the surface until no powder is visible.
- 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 3).
- 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 4).

If foam forms, let the 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 RELPREVV remains stable for up to 24 hours in the vial.

STEP 4 INJECTING ZYPREXA RELPREVV

Dose	Final Volume to Inject
150 mg	1 mL
210 mg	1.4 mL
300 mg	2 mL
405 mg	2.7 mL

Refer to the table above to determine the final volume to inject. **Suspension concentration is 150 mg/mL ZYPREXA RELPREVV.**

! 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.

- Attach a new safety needle to the syringe.
- Slowly withdraw the desired amount into the syringe.
- !** SOME EXCESS PRODUCT WILL REMAIN IN THE VIAL.
- Engage the needle safety device and remove needle from syringe.
- For administration, select the 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needle with protection device. For obese patients, a 2-inch (50 mm), 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 GLUTEAL 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.

JELCO[™] HYPODERMIC NEEDLE-PRO[®] SYRINGE AND NEEDLE with NEEDLE PROTECTION DEVICE

1. DESCRIPTION

The Hypodermic Needle-Pro Syringe and Needle is a sterile, latex-free, single-use device. It includes a needle, needle safety sheath, and syringe. The Needle-Pro device can be used with a Luer slip or Luer lock syringe.

2. INDICATIONS FOR USE

This device is intended for injection or aspiration of fluids. The needle protection device covers the needle after use to help prevent needle sticks.

3. CONTRAINDICATIONS

None known.

4. WARNINGS

- 4.1 A needle stick with a contaminated needle may cause infectious diseases.
- 4.2 Intentional disengagement of the Needle-Pro device may result in a needle stick with a contaminated needle.
- 4.3 Bent or damaged needles can result in breakage or damage to the tissue or accidental needle puncture. If the needle is bent or damaged, no attempt should be made to straighten the needle or engage the Needle-Pro device. The Needle-Pro device may not properly contain a bent needle and/or the needle could puncture the needle protection device, which may result in a needle stick with a contaminated needle.
- 4.4 Mishandling of the needle protection device may cause needles, especially short or small gauge needles, to bend whereby they protrude from the needle protection sheath, which may result in a contaminated needle-stick.
- 4.5 Do not use with paraldehyde.

5. INSTRUCTIONS FOR USE

- 5.1 Peel blister and remove device.
- 5.2 Insure needle is firmly seated on the Needle-Pro device with a push and a clockwise twist, then pull the needle cap straight away from the needle.
- 5.3 After procedure is completed, press the needle into the sheath using a one-handed technique. Perform a one-handed technique by GENTLY pressing the sheath against a flat surface. AS THE SHEATH IS PRESSED, THE NEEDLE IS FIRMLY ENGAGED INTO THE SHEATH (see Figures 1, 2, and 3).



Figures 1, 2, and 3: Firmly press needle into sheath.

- 5.4 Visually confirm that the needle is fully engaged into the needle protection sheath.
- 5.5 Only remove the Needle-Pro device with engaged needle from the syringe when required by a specific medical procedure.
Remove by grasping the Luer hub of the needle protection device with thumb and forefinger, keeping the free fingers clear of the end of the device containing the needle point.
- 5.6 After use, place sharps in a suitable sharps container. Dispose of contaminated product in a safe manner according to Centers for Disease Control and Prevention, USA and federal/state/local regulations (EPA, OSHA), and healthcare facility guidelines or local equivalent.

NON-PYROGENIC



CAUTION: Follow standard infection control procedures as specified by the Centers for Disease Control and Prevention (USA) or local equivalent.

The Smiths Medical, Jelco design mark; Needle-Pro; Portex; and the color orange applied to the needle protection device are trademarks of the Smiths Medical family of companies. The Symbol © indicates the trademark is registered in the US Patent and Trademark Office and certain other countries.

The products described are covered by one or more of the following: US Patent No. 4,982,842; its counterpart foreign patent(s); and other US and/or foreign pending patents.

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The JELCO[™] Hypodermic Needle-Pro[®] is manufactured by Smiths Medical ASD, Inc. Keene, NH 03431 USA

www.smiths-medical.com

Smiths Medical International Ltd., Hythe, Kent, CT21 6JL, UK is the EU representative for the Hypodermic Needle-Pro

smiths medical
bringing technology to life

ZYPREXA[®] Relprevv[™]
*(olanzapine) For Extended Release
Injectable Suspension*

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVV, including Boxed Warnings.



PRESCRIBER 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 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

License Number: _____ State of Issue: _____

Treatment Facility Name (Where you see your patients): _____
If you see your patients at multiple locations please contact the Coordinating Center

Address Line 1: _____

Address Line 2: _____

City: _____ Zip: _____

Phone: _____ Alternate Phone: _____

Fax: _____ Prescriber Email: _____

Preferred Method of Communication: Email Fax

FOR POSITION ONLY

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

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. **NOTE: A Spanish version of this form is available on-line www.zyprexarelprevvprogram.com**
- ▶ **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.

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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.

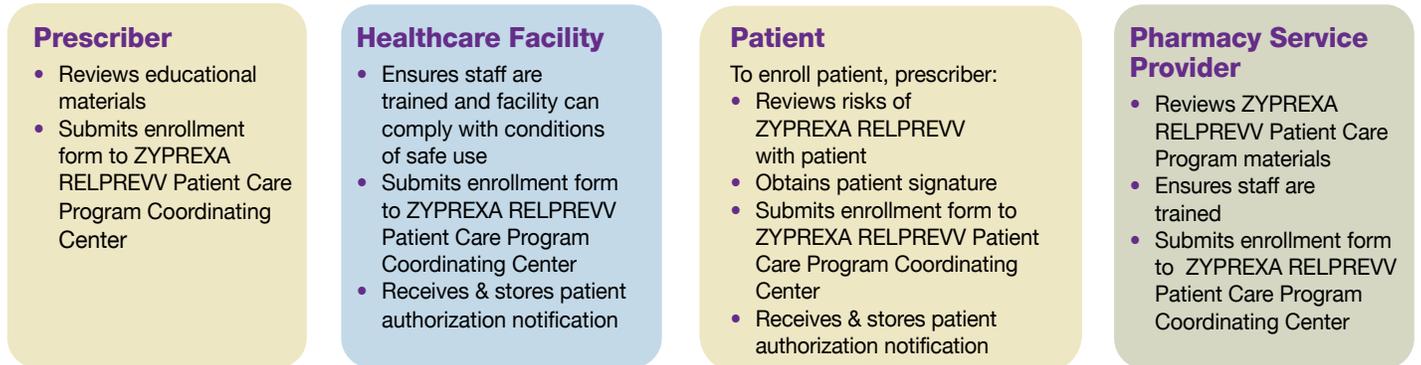
BOXED WARNINGS

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

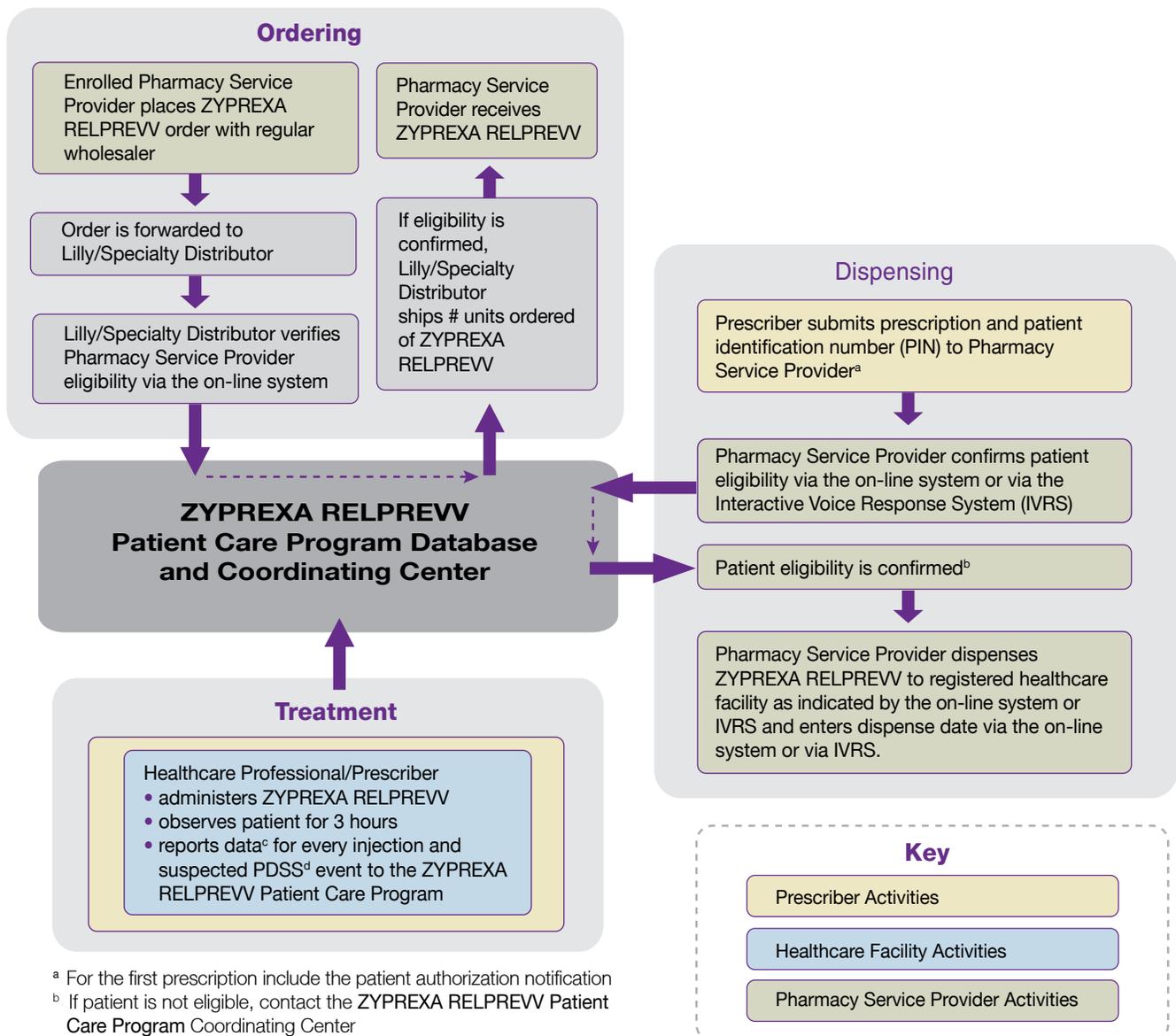
Post-Injection Delirium/Sedation Syndrome — Adverse events with signs and symptoms consistent with olanzapine overdose, in particular, sedation (including coma) and/or delirium, have been reported following injections of ZYPREXA RELPREVV. ZYPREXA RELPREVV must be administered in a registered healthcare 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



ZYPREXA RELPREVV Patient Care Program Process Flow



^a For the first prescription include the patient authorization notification
^b If patient is not eligible, contact the ZYPREXA RELPREVV Patient Care Program Coordinating Center
^c Data entry is required for patient to be eligible for refill
^d PDSS = post-injection delirium/sedation syndrome

ZYPREXA RELPREVV Patient Care Program Coordinating Center Contact Information

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: 7:00am – 9:00pm 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 RELPREVV Patient Care Program in order to prescribe ZYPREXA RELPREVV.

Three Steps to Prescriber Enrollment:

1. Review:

Attend a training or review the following educational materials:

- ZYPREXA RELPREVV Patient Care Program Instructions Brochure (this document)
- Healthcare Professional Training Slide Presentation with text notes or Recorded Presentation with participant guide, available at www.zyprexarelprevvprogram.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.

Enrolling in the ZYPREXA RELPREVV 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 RELPREVV through a pharmacy: Provide a prescription to a registered pharmacy.

Prescribers who order and dispense ZYPREXA RELPREVV through buy 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 RELPREVV 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.

Prescriber Information

The prescriber is responsible for enrolling the **patient** in the ZYPREXA RELPREVV 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 RELPREVV Patient Care Program.
- Patient has been provided with a Medication Guide and informed about the risks associated with the administration of ZYPREXA RELPREVV.
- Patient has been informed about the Patient Care Program guidelines.

2. Complete/Sign:

Complete a Patient Registration Form and have either the patient or guardian sign the form. Provide the Patient Registration Form-Patient Copy version to the patient or 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 RELPREVV 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 RELPREVV Patient Care Program within **24 hours of awareness of the event**. The ZYPREXA RELPREVV 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.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 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.

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.

Healthcare Facility Information

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 with participant guide, available at www.zyprexarelprevvprogram.com
 - Reconstitution & Administration Training Video and Poster

- Required for staff working with patients post-injection:
 - Healthcare Professional Training Slide Presentation with text notes or Recorded Presentation
 - ZYPREXA RELPREVV Patient Care Program Instructions Brochure (this document)

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. 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.zyprexareprevvprogram.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.

Once the ZYPREXA RELPREVV Patient Care Program Coordinating Center receives the completed registration form, the pharmacy service provider will be sent a username and password, which allows secured access to the on-line Patient Care Program system and interactive voice response system (IVRS).

Pharmacy Service Provider Information

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, enter the date of dispensing 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 (If the healthcare facility cannot be confirmed, call the Coordinating Center).
- The system will indicate the patient's eligibility to receive ZYPREXA RELPREVV.
 - If eligible, enter the date of dispensing 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.

Pharmacy Service Provider Information

Call the Coordinating Center Help Desk – call 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 enters the date of dispensing.
 - 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.

SINGLE PATIENT INJECTION FORM

zyprexaRelprevv
*(olanzapine) For Extended Release
 Injectable Suspension*

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.: (PIN)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Injection Facility Name: _____
Patient Name:	_____	_____
	First	MI Last
Date of Birth:	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
	month	day year

PDSS since the last visit? (After the patient left the office, following delirium/sedation syndrome?) _____ occurrence post-injection

- Yes
- No
- If Yes, has the prescriber changed?
 - Yes No

FOR POSITION ONLY

ZYPREXA RELPREVV TREATMENT

Date of Injection: - -

month day year

Time of ZYPREXA RELPREVV injection: :

24-hour clock

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.

PRESCRIBER 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 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

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.

Prescriber Signature

DATE:

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month day year



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: _____

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 staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.
- 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 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.
- 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 pharmacy.

Pharmacist-in-Charge Signature

DATE:

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month day year

Phone 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com



BUY & BILL* PHARMACY SERVICE PROVIDER REGISTRATION FORM

BUY & BILL
PHARMACY

zyprexaRelprevv[™]
(olanzapine) For Extended Release
Injectable Suspension

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: _____

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 staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.
- 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 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.
- 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:

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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.

Phone 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com

Version .101 28Oct2009

CONFIDENTIAL

Page 1 of 1

HEALTHCARE FACILITY 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 healthcare facility may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

HEALTHCARE FACILITY INFORMATION

Enrollment Reenrollment

Healthcare Facility Name: _____

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: _____
(if different from above) (if different from above)

Email: _____

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

Facility Name: _____

Phone: _____ Fax: _____
(if different from above) (if different from above)

Email: _____

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

Facility Name: _____

Phone: _____ Fax: _____
(if different from above) (if different from above)

Email: _____

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

Facility Name: _____

Phone: _____ Fax: _____
(if different from above) (if different from above)

Email: _____

If additional Delegates are required contact the Coordinating Center.



HEALTHCARE FACILITY REGISTRATION FORM

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 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:

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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.



PATIENT REGISTRATION 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 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 of Patient

DATE: [] [] - [] [] - [] [] [] []
month day year

Printed Name of Patient

Printed Name of Guardian (if applicable)

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

Signature of Prescriber

DATE: [] [] - [] [] - [] [] [] []
month day year

Printed Name of Prescriber



PATIENT REGISTRATION FORM COPY

PATIENT
COPY



Provide this copy of the ZYPREXA RELPREVV Patient Care Program Patient Registration Form to the patient or guardian upon enrollment.

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

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.: (PIN)

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

 Healthcare Facility Staff Member Signature

DATE: - -
 month day year

Healthcare Facility Staff Member Name (print): _____



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

- -

	Patient Info.	Patient Info.	Patient Info.
Patient No.: (PIN)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Patient Name:	First Name _____ MI Last Name _____	First Name _____ MI Last Name _____	First Name _____ MI Last Name _____
Date of Birth:	_____ - _____ - _____ month day year	_____ - _____ - _____ month day year	_____ - _____ - _____ month day year
PDSS since last visit? (check one)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> No
Time of Injection (24-hour clock)	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
Dose of Injection (check one)	<input type="checkbox"/> 150 mg <input type="checkbox"/> 210 mg <input type="checkbox"/> 300 mg <input type="checkbox"/> 405 mg <input type="checkbox"/> Other dose _____ mg	<input type="checkbox"/> 150 mg <input type="checkbox"/> 210 mg <input type="checkbox"/> 300 mg <input type="checkbox"/> 405 mg <input type="checkbox"/> Other dose _____ mg	<input type="checkbox"/> 150 mg <input type="checkbox"/> 210 mg <input type="checkbox"/> 300 mg <input type="checkbox"/> 405 mg <input type="checkbox"/> Other dose _____ mg
Observed at least 3 hours post-injection? (check one)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
PDSS during onsite observation? (check one)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> 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)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Following the injection, was the patient accompanied from the facility? (check one)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Signature	_____ Healthcare Facility Staff Member Signature <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> month day year _____ Healthcare Facility Staff Member Name (print)	_____ Healthcare Facility Staff Member Signature <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> month day year _____ Healthcare Facility Staff Member Name (print)	_____ Healthcare Facility Staff Member Signature <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> month day year _____ Healthcare Facility Staff Member Name (print)



POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

zyprexaRelprevv[™]
(olanzapine) For Extended Release
Injectable Suspension

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: :
24-hour clock

Convenience Kit Package

Lot # _____

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

- | | | |
|--|--|---|
| <input type="checkbox"/> 1 - 15 minutes | <input type="checkbox"/> 46 - 60 minutes | <input type="checkbox"/> 121 - 150 minutes (2 ½ hours) |
| <input type="checkbox"/> 16 - 30 minutes | <input type="checkbox"/> 61 - 90 minutes (1 ½ hours) | <input type="checkbox"/> 151 - 180 minutes (3 hours) |
| <input type="checkbox"/> 31 - 45 minutes | <input type="checkbox"/> 91 - 120 minutes (2 hours) | <input type="checkbox"/> 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).

- | | | | |
|---|---|--|--|
| <input type="checkbox"/> Aggressiveness | <input type="checkbox"/> Coma | <input type="checkbox"/> Hypertension | <input type="checkbox"/> Tachycardia |
| <input type="checkbox"/> Agitation | <input type="checkbox"/> Confusion | <input type="checkbox"/> Hypotension | <input type="checkbox"/> Various extrapyramidal symptoms |
| <input type="checkbox"/> Anxiety | <input type="checkbox"/> Convulsion/Seizure | <input type="checkbox"/> Other cognitive impairment | <input type="checkbox"/> Weakness |
| <input type="checkbox"/> Aspiration | <input type="checkbox"/> Delirium | <input type="checkbox"/> Possible neuroleptic malignant syndrome | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Ataxia | <input type="checkbox"/> Disorientation | <input type="checkbox"/> Reduced level of consciousness | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Cardiac arrhythmias | <input type="checkbox"/> Dizziness | <input type="checkbox"/> Respiratory depression | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Cardiopulmonary arrest | <input type="checkbox"/> Dysarthria | <input type="checkbox"/> Sedation | <input type="checkbox"/> 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: - - OR Ongoing
month day year

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

Treatment Medication Name	Dose	Duration of Use (in Days)



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

- | | | | |
|---|------------------------------------|---|--|
| <input type="checkbox"/> Assisted ventilation | <input type="checkbox"/> EEG | <input type="checkbox"/> MRI | <input type="checkbox"/> Urine drug screen |
| <input type="checkbox"/> Brain CT | <input type="checkbox"/> IV fluids | <input type="checkbox"/> Observation/symptomatic management | <input type="checkbox"/> Vital sign monitoring |
| <input type="checkbox"/> ECG | <input type="checkbox"/> Labs | <input type="checkbox"/> Restraints | <input type="checkbox"/> 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

Prior Medication Name	Dose	Duration of Use			
		Number	Choose One		
			<input type="checkbox"/> Days	<input type="checkbox"/> Months	<input type="checkbox"/> Years
			<input type="checkbox"/> Days	<input type="checkbox"/> Months	<input type="checkbox"/> Years
			<input type="checkbox"/> Days	<input type="checkbox"/> Months	<input type="checkbox"/> Years
			<input type="checkbox"/> Days	<input type="checkbox"/> Months	<input type="checkbox"/> Years
			<input type="checkbox"/> Days	<input type="checkbox"/> Months	<input type="checkbox"/> Years

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

- | | | | |
|--|---------------------------------------|--|--|
| <input type="checkbox"/> Alcohol | <input type="checkbox"/> Barbiturates | <input type="checkbox"/> Cocaine | <input type="checkbox"/> Opiates |
| <input type="checkbox"/> Amphetamines/Methamphetamines | <input type="checkbox"/> Cannabinoid | <input type="checkbox"/> Hallucinogens | <input type="checkbox"/> Phencyclidine |

Event reported by: _____
First MI Last

Title/Occupation: _____

If agent of the Prescriber, name of Prescriber: _____
First MI Last



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(olanzapine) For Extended Release
Injectable Suspension

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](#)

[Important Safety Information](#)

[Pharmacy Finder](#)

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVV, including Boxed Warnings.

[PRIVACY POLICY](#)

ZYPREXA RELPREVV Patient Care Program

[Log In](#)

User Name

Password

[Enter](#)

[How Do I Enroll](#)

[FORGOT PASSWORD](#)

[PRIVACY POLICY](#)

In order to enroll in the ZYPREXA RELPREVV Patient Care Program, you must first complete the required training then submit the appropriate registration form.

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ZYPREXA RELPREVV Patient Care Program

How Do I Enroll

3 STEPS TO ENROLLMENT

1. Review Training Materials

- [On-line Training](#)

OR

- [Order Training Materials](#)

2. Complete Registration Form

3. Submit on-line or via fax

Once enrollment is completed, a user name and password for accessing the ZYPREXA RELPREVV Patient Care Program system will be sent to you via fax or email.

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ZYPREXA RELPREVV Patient Care Program

[Contact Us](#)

ZYPREXA RELPREVV PATIENT CARE PROGRAM CONTACT INFORMATION

ZYPREXA RELPREVV Patient Care Program

Phone: 1-877-772-9390

Fax: 1-877-772-9391

ZYPREXA RELPREVV Patient Care Program Coordinating Center Hours of Operation

Monday – Friday: 7am – 9pm ET

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ZYPREXA RELPREVV Patient Care Program

On-line Training

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)**

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ZYPREXA RELPREVV Patient Care Program

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](#).

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ZYPREXA RELPREVV Patient Care Program

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 RELPREVV 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](#).

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ZYPREXA RELPREVV Patient Care Program

Required Pharmacy Service Provider Training

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.*

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ZYPREXA RELPREVV Patient Care Program

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 Form](#)

[Patient Registration Form \(English\)](#)

- [Patient Copy](#)

[Patient Registration Form \(Spanish\)](#)

- [Patient Copy](#)

[Healthcare Facility Registration Form](#)

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ZYPREXA RELPREVV Patient Care Program

Pharmacy Finder

Pharmacy Finder

Search For By

Name	Address 1	Address 2	Address 3	City	State	Zip	Phone #	Distance	Map

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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
- PDSS Case Study Video (DVD)
- Medication Guide
- Prescribing Information

*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 RELPREVV Patient Care Program Instructions Brochure

Training Materials Available as Individual Items:

ZYPREXA RELPREVV 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)

English Patient Materials	Spanish Patient Materials
<input type="checkbox"/> 10 Wristbands	<input type="checkbox"/> 10 Wristbands
<input type="checkbox"/> 10 ID cards	<input type="checkbox"/> 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 (English) - 5 patient forms/pack
 Patient Registration Form (US Spanish) - 5 patient forms/pack

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](#).

You may also contact your Lilly sales representative to request materials and resources.

Submit



Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- NDA-22173	----- ORIG-1	----- ELI LILLY CO	----- ZYPREXA/ADHERA

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
12/11/2009