

Initial REMS Approval: 12/2009
Most Recent Modification: 04/2020

NDA 22-173
Zyprexa® Relprevv™ (olanzapine)

For Extended Release Injectable Suspension

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Zyprexa Relprevv Patient Care Program

I. GOAL

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

1. ensuring Zyprexa Relprevv is prescribed only by certified prescribers, dispensed only by certified dispensers, and dispensed for use only in certified healthcare facilities with ready access to emergency response services, and dispensed for use only with documentation of safe use conditions;
2. informing healthcare providers and patients about the risks and the need for continuous observation of patients for at least 3 hours in certified health care facilities; and
3. establishing long-term safety and safe use of Zyprexa Relprevv through periodic monitoring for the risk of PDSS events and by enrolling all patients who receive Zyprexa Relprevv in the Zyprexa Relprevv Patient Care Program Registry.

II. REMS ELEMENTS

A. Medication Guide

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

The Medication Guide is part of the REMS and is appended.

B. Communication Plan

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

C. Elements to Assure Safe Use

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

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 health care settings (e.g. , hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection;
 - iv. will enroll all patients in the Zyprexa Relprevv Patient Care Program Registry prior to prescribing Zyprexa Relprevv by completing the Patient Registration Form;
 - v. will review the Zyprexa Relprevv Medication Guide with each patient or the patient's legal guardian prior to prescribing; and,
 - vi. understand that the Zyprexa Relprevv Patient Care Program coordinating center may contact the prescriber to resolve discrepancies, to obtain information about a patient, or to conduct occasional surveys.
- b. The certified prescriber will be retrained and recertified every 3 years from time of enrollment.
- c. Lilly may disenroll prescribers that are noncompliant with the program requirements.

- d. Lilly will maintain a validated and secured database of all certified prescribers, as well as a database of the completed data forms. The database links each reported PDSS event to the enrolled patient and the associated prescriber.
 - e. The following prescriber materials are part of the REMS and are appended:
 1. Healthcare Professional Training
 2. Zyprexa Relprevv Patient Care Program Instructions Brochure
 3. Prescriber Registration Form
- 2. Zyprexa Relprevv will only be dispensed by pharmacies and health-care settings under FDCA 505-1(f)(3)(C) who are specially certified under FDCA 505-1(f)(3)(B).**
- a. Lilly will ensure that to be certified to dispense Zyprexa Relprevv, each pharmacy and health-care setting will be enrolled in the Zyprexa Relprevv Patient Care Program. Lilly will ensure that to become enrolled the pharmacy and health-care setting staff have been educated about the requirements of the Zyprexa Relprevv Patient Care Program.

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

- i. Each pharmacy and health-care setting where Zyprexa Relprevv is dispensed for use in other certain health-care settings will designate a representative who will review the Zyprexa Relprevv Patient Care Program Instruction Brochure. The designated representative will complete and sign the Pharmacy Registration Form or the Buy and Bill Registration Form. In signing the form, the representative is required to indicate that they understand and attest that:
 - a) I have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;
 - b) I will ensure that all appropriate pharmacy staff are trained and have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;
 - c) I will ensure that all appropriate pharmacy staff understand that Zyprexa Relprevv can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services that can allow for continuous patient monitoring for at least 3 hours post-injection;
 - d) I will ensure that pharmacy staff will verify that the patient is enrolled in the Zyprexa Relprevv Patient Care Program Registry prior to dispensing each prescription/refill by accessing the system;

- e) I will ensure that pharmacy staff will not dispense Zyprexa Relprevv directly to patients;
 - f) I will ensure pharmacy staff report the date of each Zyprexa Relprevv dispensing to the Zyprexa Relprevv Patient Care Program; and
 - g) I understand that the Zyprexa Relprevv Patient Care Program coordinating center may contact the pharmacy to clarify information provided or obtain information about the patient.
- ii. Each health-care setting where Zyprexa Relprevv is dispensed and administered to the patient will designate a representative who will review the Zyprexa Relprevv Patient Care Program Instruction Brochure. The designated representative will complete and sign the Healthcare Facility Registration Form. In signing the form, the representative is required to indicate that they understand and attest that:
- a) I have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;
 - b) I will ensure that all appropriate staff are trained and have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;
 - c) I will ensure that all appropriate staff understand that Zyprexa Relprevv can only be dispensed for use in certain health-care settings (e.g., hospitals, clinics) that have ready access to emergency response services that can allow for continuous patient monitoring for at least 3 hours post-injection;
 - d) I will ensure the health-care setting has systems, protocols, or other measures to ensure that Zyprexa Relprevv is only administered to patients enrolled in the program and that patients are continuously monitored for at least 3 hours post-injection for suspected PDSS;
 - e) I will ensure that appropriate staff will verify that the patient is enrolled in the Zyprexa Relprevv Patient Care Program Registry prior to each injection by accessing the system;
 - f) I will ensure that the Medication Guide is provided to the patient or the patient's legal guardian prior to each injection;
 - g) I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours; and
 - h) I understand that the Zyprexa Relprevv Patient Care Program coordinating center may contact the health-care setting to clarify information provided or obtain information about the patient.
- b. Certified dispensers will be recertified every 3 years from the time of enrollment.

- c. Lilly may disenroll dispensers that are noncompliant with the program requirements.
 - d. The following materials are part of the REMS and are appended:
 1. Pharmacy Registration Form
 2. Buy & Bill Pharmacy Service Provider Registration Form
 3. Zyprexa Relprevv Healthcare Professional Training
 4. Zyprexa Relprevv Reconstitution and Administration Training
 5. Zyprexa Relprevv Patient Care Program Instructions Brochure
 6. Healthcare Facility Registration Form
- 3. Zyprexa Relprevv will be dispensed to patients with evidence or other documentation of safe-use conditions under FDCA 505-1(f)(3)(D).**
- a. Lilly will ensure that certified dispensers will verify that each patient is eligible to receive Zyprexa Relprevv prior to dispensing each prescription/refill of Zyprexa Relprevv by accessing the Zyprexa Relprevv Patient Care Program and ensuring the patient is enrolled in the Zyprexa Relprevv Patient Care Program Registry and the prescriber is certified.
- 4. Each patient using Zyprexa Relprevv will be subject to certain monitoring under 505-1(f)(3)(E).**
- a. For each injection of Zyprexa Relprevv, the practitioner or health-care facility staff that administers Zyprexa Relprevv must monitor the patient continuously for at least 3 hours.
- 5. Each patient using the drug will be enrolled in a registry under 505-1(f)(3)(F).**
- a. Lilly will ensure that certified prescribers enroll each patient treated with Zyprexa Relprevv in the Zyprexa Relprevv Patient Care Program Registry and assign a unique identifying number before Zyprexa Relprevv is dispensed to each enrolled patient. Unless otherwise excepted under section 5e, Lilly will ensure that, to become enrolled, each patient or patient's legal guardian signs the Patient Registration Form indicating that:
 - i. they understand that the patient must enroll in the Zyprexa Relprevv Patient Care Program Registry to receive Zyprexa Relprevv;
 - ii. they agree to have patient information entered in the Zyprexa Relprevv Patient Care Program Registry;
 - iii. the doctor has explained the risk and benefits of treatment with Zyprexa Relprevv;
 - iv. they have received a copy of the Medication Guide;

- v. they understand that the patient will be observed at the clinic for 3 hours after each injection;
 - vi. they understand that the patient must be accompanied from the health-care facility to their destination;
 - vii. they understand that the patient must not use heavy machinery for the rest of the day on which the injection was administered;
 - viii. they agree to seek medical care right away if the patient has a reaction such as excessive sleepiness, dizziness, confusion, difficulty talking, difficulty walking, muscle stiffness or shaking, weakness, irritability, aggression, anxiety, increase in blood pressure or convulsions;
 - ix. they agree to contact the physician if the patient has a reaction to Zyprexa Relprevv; and
 - x. they may be asked to complete occasional surveys about their understanding of the risks and benefits of treatment with Zyprexa Relprevv.
- b. Lilly will ensure that health-care settings where Zyprexa Relprevv is administered record and submit the following information for each patient after each injection by completing either the Single or Multiple Patient Injection Form and returning this form to the Zyprexa Relprevv Patient Care Program coordinating center:
- i. injection date and time;
 - ii. dose;
 - iii. verification that the patient was continuously observed at the healthcare facility for at least 3 hours;
 - iv. verification that the patient was alert, oriented, and absent of any signs and symptoms of PDSS prior to being released from the health-care facility;
 - v. verification that the patient was accompanied upon leaving the health-care facility;
 - vi. verification that the patient or the patient's legal guardian was given a Medication Guide prior to this injection;
 - vii. any report of a PDSS event since the previous Zyprexa Relprevv injection; and
 - viii. verification that the health-care setting contacted the prescriber if the patient experienced a PDSS event.

- c. Lilly will ensure that certified prescribers record and submit the following information for any report of PDSS in a patient administered Zyprexa Relprevv by completing the Post-Injection Delirium/Sedation Form and returning it to the Zyprexa Relprevv Patient Care Program coordinating center:
 - i. summary of the PDSS event, including signs and symptoms of any event and a detailed timeline of the course of events related to injection;
 - ii. demographic characteristics of the patient (age, gender, race, height, weight, medical conditions, geographical location);
 - iii. Zyprexa Relprevv dose;
 - iv. type and timing of interventional treatment or therapy administered;
 - v. outcome of the PDSS event;
 - vi. concomitant medications prior to and at the time of PDSS occurrence; and
 - vii. preexisting or concurrent medical conditions.
- d. The following materials are part of the REMS and are appended:
 - 1. Patient Registration Form
 - 2. Single Patient Injection Form
 - 3. Multiple Patient Injection Form
 - 4. Post-Injection Delirium/Sedation Syndrome Form
- e. In situations where a patient is under a court order for involuntary psychiatric treatment, which order permits the administration of medications without patient consent and/or against the patient's wishes, and where no guardian has been appointed for the patient, such patient may be enrolled in the Zyprexa Relprevv Patient Care Program Registry without patient signature. However, the Patient Registration Form must clearly show that said court order is in place and the duration of the court order. The information required under section 5(a) iii should still be shared with the patient, and the provisions of sections 5b, 5c, and 5d shall still apply.
- f. Patients enrolled under section 5e shall be considered enrolled only until such time that their court order for involuntary treatment terminates, or they are discharged from their involuntary commitment by their treatment team where permitted by applicable state law. Upon such termination or discharge, the patient must be re-enrolled in the Zyprexa Relprevv Patient Care Program pursuant to the requirements of section 5a to be eligible for continued treatment with Zyprexa Relprevv. In the alternative, if an involuntary commitment is extended by court order, a new Patient Registration Form should be requested reflecting the duration of the new order.

D. Implementation System

The Implementation System will include the following. Lilly will:

- 1) Maintain a validated and secured database of all certified dispensers, as well as a database of the completed data forms. The database links each reported PDSS event to the enrolled patient and the associated dispenser.
- 2) Review distribution data to assess compliance with the requirement that Zyprexa Relprevv is only dispensed by the certified dispensers.
- 3) Assess certified dispensers' compliance with the requirement to dispense Zyprexa Relprevv for use in health-care settings that have ready access to emergency response services and can allow for continuous patient monitoring for at least 3 hours post-injection.
- 4) Based on evaluation of the implementation of elements to assure safe use provided for under Sections C2 and C3 above, and in the manner described in the REMS supporting document, take reasonable steps to improve implementation of these elements to meet the goals of the REMS.

E. Timetable for Submission of Assessments

Lilly will submit REMS assessments to the FDA annually on 29 October. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Lilly will submit each assessment so that it will be received by the FDA on or before the due date.

Medication Guide

ZYPREXA® RELPREVV™ (zy-PREX-a REL-prev) (olanzapine)

For Extended Release Injectable Suspension

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

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

Before you receive ZYPREXA RELPREVV treatment you must:

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

ZYPREXA RELPREVV may cause serious side effects, including:

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

These serious side effects are described below.

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

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

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

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

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

- a build up of acid in your blood due to ketones (ketoacidosis)
- coma
- death

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

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

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

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

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

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

What is ZYPREXA RELPREVV?

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

- hearing voices
- seeing things that are not there
- having beliefs that are not true

- being suspicious or withdrawn

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

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

What should I tell my doctor before taking ZYPREXA RELPREVV?

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

- heart problems
- seizures
- diabetes or high blood sugar levels (hyperglycemia)
- high cholesterol or triglyceride levels in your blood
- liver problems
- low or high blood pressure
- strokes or “mini-strokes” also called transient ischemic attacks (TIAs)
- Alzheimer’s disease
- narrow-angle glaucoma
- enlarged prostate in men
- bowel obstruction
- breast cancer
- thoughts of suicide or hurting yourself
- any other medical condition
- are pregnant or plan to become pregnant. It is not known if ZYPREXA RELPREVV will harm your unborn baby.
 - If you become pregnant while receiving ZYPREXA, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or go to <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/>.
- are breast-feeding or plan to breast-feed. ZYPREXA RELPREVV passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take ZYPREXA RELPREVV.

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

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

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

How should I receive ZYPREXA RELPREVV?

- ZYPREXA RELPREVV will be injected into the muscle in your buttock (gluteus) by your doctor or nurse at the clinic.
- After receiving ZYPREXA RELPREVV, you will need to stay at the clinic for at least 3 hours.
- When you leave the clinic, someone must be with you.

- Call your doctor if you do not think you are getting better or have any concerns about your condition while taking ZYPREXA RELPREVV.

What should I avoid while receiving ZYPREXA RELPREVV?

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

What are the possible side effects of ZYPREXA RELPREVV?

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

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

- feeling very hot
- feeling thirsty
- not able to produce urine

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

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

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

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

General information about ZYPREXA RELPREVV

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

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

What are the ingredients in ZYPREXA RELPREVV?

Active ingredient: olanzapine

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

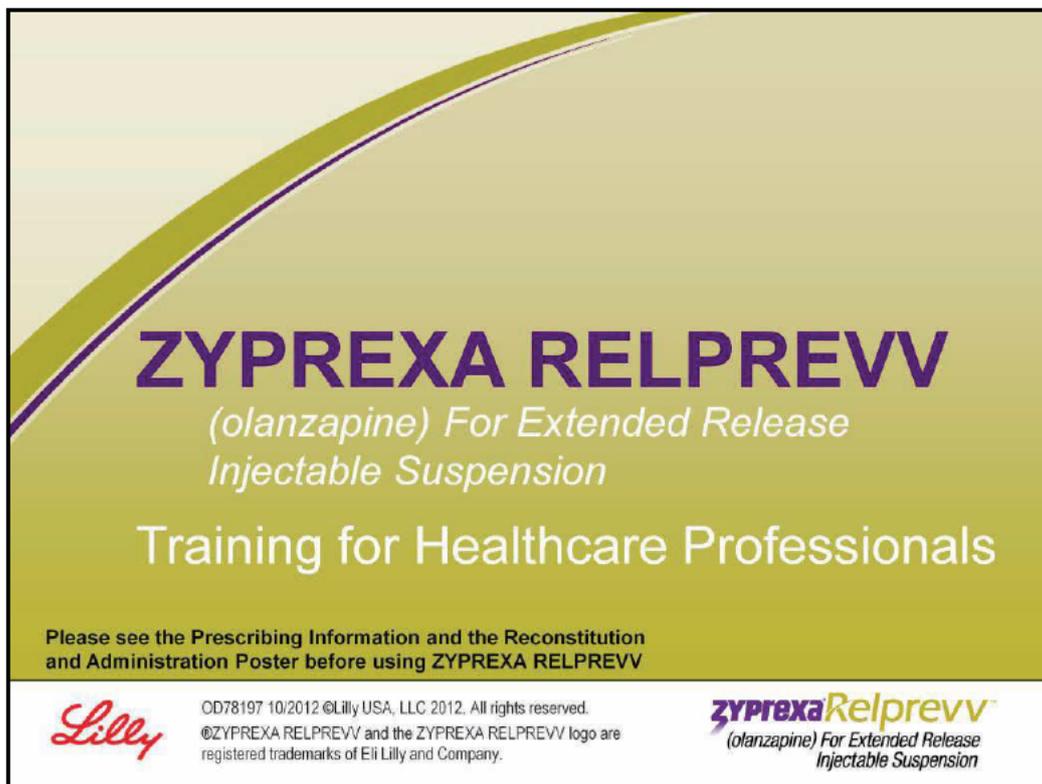
This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide revised October 22, 2019

**Marketed by: Lilly USA, LLC
Indianapolis, IN 46285, USA**

www.zyprexarelprevv.com

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The poster features a light green background with a dark green curved line at the top. The text is centered and includes the product name, its generic name and formulation, and training information for healthcare professionals. A disclaimer at the bottom left and the Lilly logo are also present.

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

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ZYPREXARelprevv™
*(olanzapine) For Extended Release
Injectable Suspension*

The goal of this presentation is to educate healthcare professionals in an effort to mitigate negative outcomes associated with ZYPREXA RELPREVV post-injection delirium/sedation syndrome (PDSS). Healthcare professionals include: physicians, nurses and any other professionals who will be involved with the care of the patient receiving the injection.

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

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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.

ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

Version 2.0 03-Aug-2012

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

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

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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

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

Version 2.0 03-Aug-2012

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

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

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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

For complete safety profile, including boxed warnings, see the full Prescribing Information. Version 2.0 03-Aug-2012

ZYPREXARelprevv
(olanzapine) For Extended Release
Injectable Suspension

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 for metabolic changes
- Identify a post-injection delirium/sedation syndrome event in your clinical practice,
- Know the conditions of safe use and how to manage the risk of post-injection delirium/sedation syndrome
- Know what to do in case a post-injection delirium/sedation syndrome event occurs.
- And finally, understand the basics of the ZYPREXA RELPREVV Patient Care Program.

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ZYPREXA RELPREVV and ZYPREXA IntraMuscular – <i>Although both have olanzapine as their active ingredient and both are injected intramuscularly, they are intended for different indications and different dosing schedules</i>		
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. <small>Version 2.0 03-Aug-2012</small>		 

It should be noted that there are 2 types of injectable olanzapine, and they are intended for very different purposes. ZYPREXA RELPREVV is the **long**-acting salt formulation of olanzapine, olanzapine pamoate, and is administered every 2 to 4 weeks for the treatment of schizophrenia in adults. ZYPREXA IntraMuscular is the **rapid**-acting injectable form of olanzapine and is indicated for the immediate treatment of **AGITATION** associated with schizophrenia or bipolar mania.

It is very important not to confuse these two products, so please also make note of the visual differences in the products and product packaging as well as differences in injection technique and dosing.

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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. Version 2.0, 03-Aug-2012

ZYPREXA Relprevv
(olanzapine) For Extended Release
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ZYPREXA RELPREVV is a combination of olanzapine and pamoic acid in the form of a crystalline salt, which is insoluble in water but has very low solubility in muscle. When injected into the gluteal muscle, the salt then dissolves slowly at the site of the injection. This results in a slow and sustained release of olanzapine into the bloodstream, allowing for administration once every 2 or 4 weeks.

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

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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



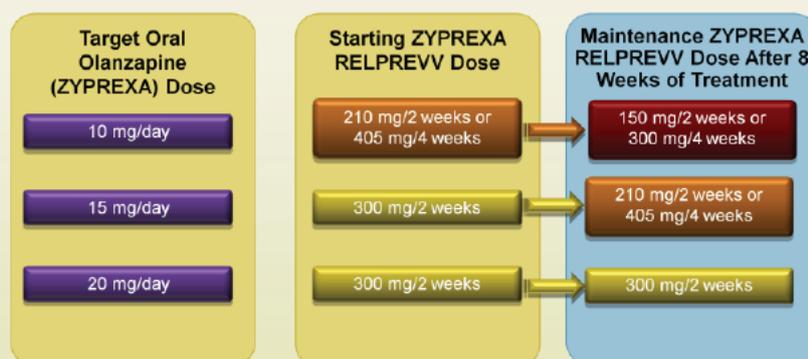
For complete safety profile, including boxed warnings, see the full Prescribing Information. Version 2.0 03-Aug-2012

ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

- ZYPREXA RELPREVV is administered by deep intramuscular gluteal injection only, using a 19 gauge, 1.5" needle to ensure a deep gluteal injection and to prevent the suspension from clogging the needle. A 2" needle may be used for obese patients. Please note that ZYPREXA RELPREVV is not approved for deltoid injections.
- ZYPREXA RELPREVV is provided as olanzapine pamoate powder, which comes in 3 vial strengths: 210, 300, and 405 mg. These strengths describe the amount of olanzapine provided in each vial. The product must be reconstituted using the diluent provided, which contains a wetting agent, a thickening agent, and an isotonic agent to allow for easier reconstitution and administration as well as patient comfort. Both the powder and the diluent are stored at room temperature and are reconstituted to a fixed concentration of 150 mg of olanzapine per milliliter.
- Once reconstituted, the suspension is stable in the vial for up to 24 hours and does not require refrigeration. However, if the suspension is not used immediately, it should be shaken to resuspend before being withdrawn into the syringe for administration.
- Once the product has been withdrawn from the vial, it should be injected immediately.
- Review the ZYPREXA RELPREVV Reconstitution and Administration Training Video and the Reconstitution and Administration Poster before reconstituting the product

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.

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ZYPREXA
Olanzapine

ZYPREXA Relprevv
(olanzapine) For Extended Release
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Transition

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

Key points

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

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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

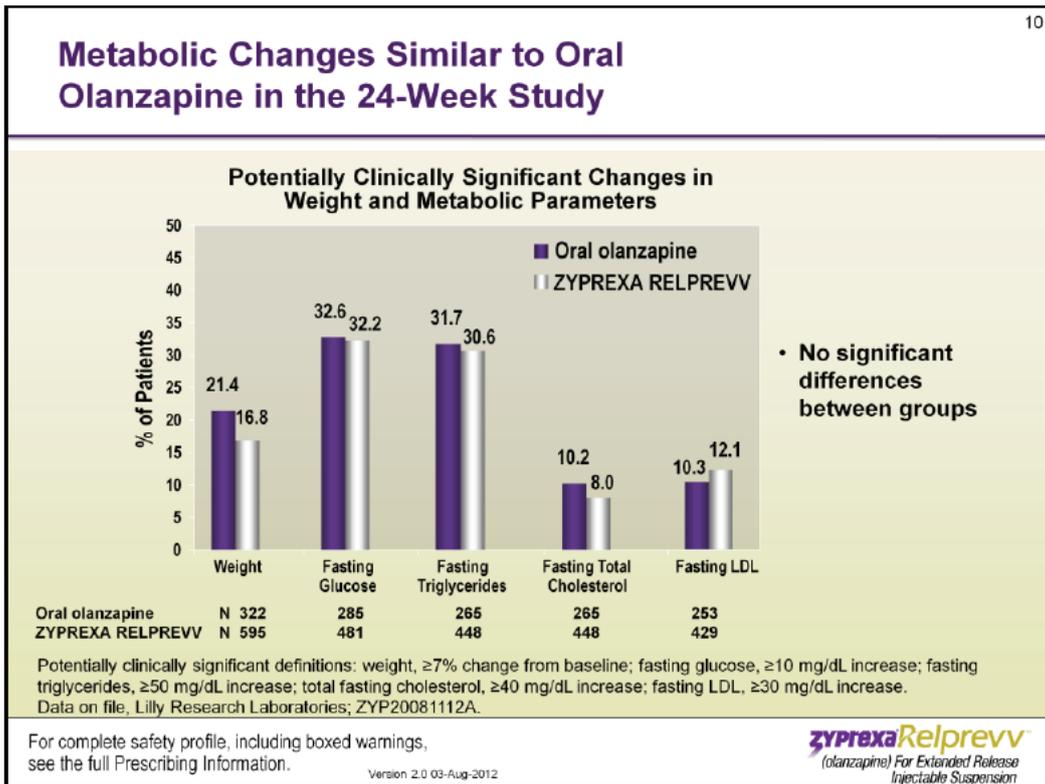
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Zyprexa Relprevv
(olanzapine) For Extended Release
Injectable Suspension

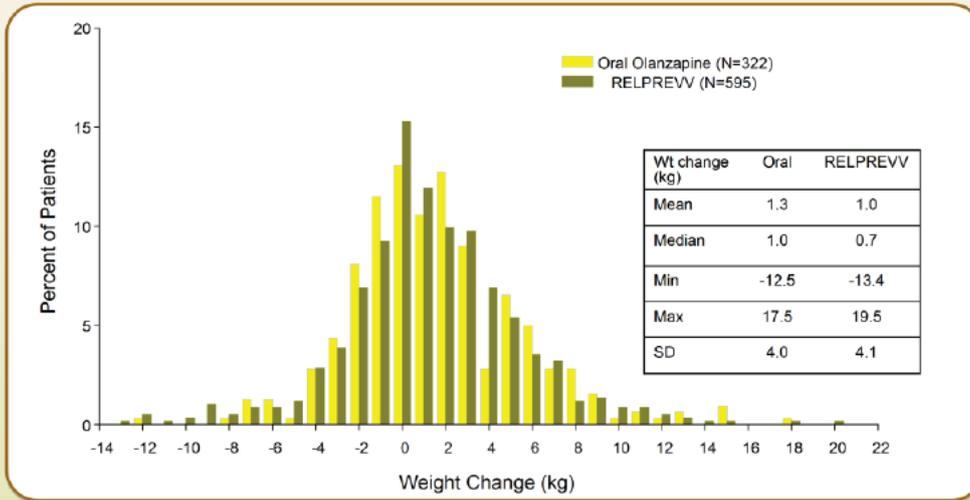
Now we will look at the safety profile for ZYPREXA RELPREVV. The overall safety of ZYPREXA RELPREVV is similar to that of oral olanzapine, with the exception of injection-related events. In a study of over 900 stabilized patients comparing ZYPREXA RELPREVV and oral olanzapine, there were no significant differences in the most commonly reported adverse events. Weight gain was the most commonly reported event in both groups.



Data from the 24-week study comparing ZYPREXA RELPREVV to oral olanzapine also indicated no significant differences in the percentage of patients experiencing a potentially clinically significant change from baseline in weight, fasting glucose, fasting triglycerides, fasting total cholesterol, or fasting LDL cholesterol.

The results suggest that the metabolic profile is comparable to that of oral olanzapine.

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

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ZYPREXA Relprevv
 (olanzapine) For Extended Release
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Looking at the weight change seen in this study in more detail, there was no difference in the pattern of weight gain or loss in patients treated with ZYPREXA RELPREVV versus those treated with oral olanzapine. The mean weight change in both groups was a gain of approximately one kilogram.

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 (%)

Data on file, Lilly Research Laboratories, ZYP20081112B

*P<.05 versus 150 mg/2 wk

†P<.05 versus 405 mg/4 wk

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

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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

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ZYPREXA Relprevv
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- Because the active ingredient of ZYPREXA RELPREVV is the same as oral olanzapine, clinicians should follow the same guidance with regard to metabolic changes that they would for the oral formulation.
- Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including olanzapine. Relative risk estimates are inconsistent, and the association between atypical antipsychotics and increases in blood glucose appear to fall in a continuum. Olanzapine appears to have a greater association with increases in blood glucose levels than some other atypicals.
- Patients on olanzapine should be monitored regularly for worsening of glucose control. Benefits and risks of olanzapine should be considered when prescribing the product to patients with diabetes and to those with borderline hyperglycemia.
- Patients starting treatment with olanzapine should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment.
- Fasting blood glucose tests should be conducted in patients who develop symptoms of hyperglycemia during treatment

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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

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

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- Undesirable lipid alterations have been observed during treatment with olanzapine. Clinical monitoring, including baseline and follow-up lipid evaluations, is advised.
- Clinically significant and sometimes very high elevations in triglycerides have been observed during olanzapine use. Modest mean increases in total cholesterol have also been observed.
- Patients should be monitored regularly for weight gain during treatment with olanzapine. Prescribers should consider the potential consequences of weight gain prior to initiating treatment.

15

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.

ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

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In premarketing clinical trials, an unexpected degree of delirium and/or sedation was reported in a small number of patients with schizophrenia shortly after receiving an injection. This event has been termed Post-injection Delirium/Sedation Syndrome, or PDSS.

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

Nevertheless, it is important to be aware that a PDSS event can occur in any patient at any injection.

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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.

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What is Post-injection Delirium/Sedation Syndrome?

- These events appear to be related to excessive olanzapine plasma concentrations and presentation of the events are consistent with many symptoms of oral olanzapine overdose. While the precise mechanism of these events remains unknown, ZYPREXA RELPREVV is more soluble in blood than in muscle. Contact with a substantial volume of blood would lead to faster dissolution (as the olanzapine disassociates from the pamoic acid), resulting in higher than expected olanzapine concentrations. There are several ways that such contact could occur, including direct or partial injection into the vasculature, blood vessel injury during the injection, or as the result of an extravascular bleed around the vessel.
- Most patients who experienced such an event developed symptoms related to sedation and/or delirium. Sedation could range from mild to severe, and in one case included coma lasting up to 12 hours. Symptoms related to delirium could include confusion, disorientation, agitation, anxiety, and other cognitive impairment. Other symptoms that were noted in some cases included extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension, or convulsions.
- PDSS events typically began with milder symptoms which then progressed in severity and/or number. The clinical presentation has sometimes been described as appearing similar to that of alcohol intoxication.
- Time after injection to event ranged from soon after injection to greater than 3 hours after injection.

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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

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(olanzapine) For Extended Release
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There have been no clinically significant decreases in blood pressure and no respiratory depression noted in any of the PDSS events in the premarketing clinical trials. Approximately 15% of cases experienced temporary unconsciousness. In most cases, patients were hospitalized for further observation and/or treatment. Two patients were intubated prophylactically following parenteral administration of benzodiazepines, with no respiratory depression noted. Concomitant medications or substances have not been shown to be risk factors for these events.

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

18

Safety Precautions at Every ZYPREXA RELPREVV Injection

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

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

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

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

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

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Safety Precautions at Every ZYPREXA RELPREVV Injection

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

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

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

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

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

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

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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

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ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

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

Safety Precautions at Every ZYPREXA RELPREVV Injection

- **Before patient leaves the healthcare facility:**
 - Confirm that the patient is alert, oriented, and without signs or symptoms of a post-injection delirium/sedation syndrome event. If PDSS is suspected, close medical supervision and monitoring should be instituted in a facility capable of resuscitation
 - Advise patients and caregivers to be vigilant for symptoms of a PDSS event for the remainder of the day and be able to obtain medical assistance if needed
 - All patients must be accompanied to their destination upon leaving the facility
- **After leaving the healthcare facility:**
 - For the remainder of the day of each injection, patients should not drive or operate heavy machinery

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

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

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

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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

For complete safety profile, including boxed warnings, see the full Prescribing Information. Version 2.0 03-Aug-2012

ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

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

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

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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

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

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ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

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

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

If ZYPREXA RELPREVV is discontinued following a PDSS event, the healthcare professional should be aware that, as with all long-acting medications, the effects of ZYPREXA RELPREVV will continue for some time after discontinuation of the drug. Treatment with alternative medication may be started when clinically indicated.

ZYPREXA RELPREVV 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.

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ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

ZYPREXA RELPREVV is available only through a controlled distribution system to registered prescribers for use in registered facilities. Participation in the ZYPREXA RELPREVV Patient Care Program is mandatory for patients, prescribers, healthcare facilities and pharmacy service providers.

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

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

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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

For complete safety profile, including boxed warnings, see the full Prescribing Information. Version 2.0 03-Aug-2012

ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

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

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

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

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Prescriber Registration

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

Prescriber obligations include:

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

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

Version 2.0 03-Aug-2012



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

Prescriber obligations include:

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

Patient Registration

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

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

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

Version 2.0 03-Aug-2012

ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

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

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

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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 or legal guardian prior to each injection
- Ensuring that the appropriate staff monitors the patient continuously for at least 3 hours
- Ensuring that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVV Patient Care Program
- Understanding the facility may be contacted by the ZYPREXA RELPREVV Patient Care Program Coordinating Center to clarify information provided or obtain information about the patient

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



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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 or **legal** guardian prior to each injection
- Ensuring that the appropriate staff monitors the patient continuously for at least 3 hours
- Ensuring that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVV Patient Care Program
- Understanding the facility may be contacted by the ZYPREXA RELPREVV Patient Care Program Coordinating Center to clarify information provided or obtain information about the patient

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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 pharmacy staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure
 - Ensuring that all appropriate pharmacy staff understand that ZYPREXA RELPREVV can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services that can allow for continuous patient monitoring for at least 3 hours post-injection
 - 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.

Version 2.0 03-Aug-2012



Zyprexa Relprev
(olanzapine) For Extended Release
Injectable Suspension

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 pharmacy staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure
- Ensuring that **all** appropriate pharmacy staff understand that ZYPREXA RELPREVV can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services that can **allow** for continuous patient monitoring for at least 3 hours post-injection
- 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

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

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ZYPREXARelprevv
(olanzapine) For Extended Release
Injectable Suspension

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 for metabolic changes
- Identify a post-injection delirium/sedation syndrome event in your clinical practice,
- Know the conditions of safe use and how to manage the risk of post-injection delirium/sedation syndrome
- Know what to do in case a post-injection delirium/sedation syndrome event occurs.
- And finally, understand the basics of the ZYPREXA RELPREVV Patient Care Program.

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

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



Enclosed Registration Forms Include:

- ▶ **Prescriber Registration**
Enrolls the prescriber to treat patients with ZYPREXA RELPREW.
- ▶ **Pharmacy Service Providers**
 - **Pharmacy Registration**
Enrolls the pharmacy to order and dispense ZYPREXA RELPREW.
 - **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 RELPREW.
- ▶ **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 RELPREW injections and monitor patients after each injection.

ZYPREXA RELPREW 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 (POSS) Form

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

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Introduction to the ZYPREXA RELPREVV Patient Care Program

Patient Care Program Overview

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

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

Post-Injection Delirium/Sedation Syndrome:

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

BOXED WARNING

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

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

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

ZYPREXA Relprevv Patient Care Program Enrollment

Prescriber

- Reviews educational materials
- Submits enrollment form to ZYPREXA Relprevv Patient Care Program Coordinating Center

Healthcare Facility

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

Patient

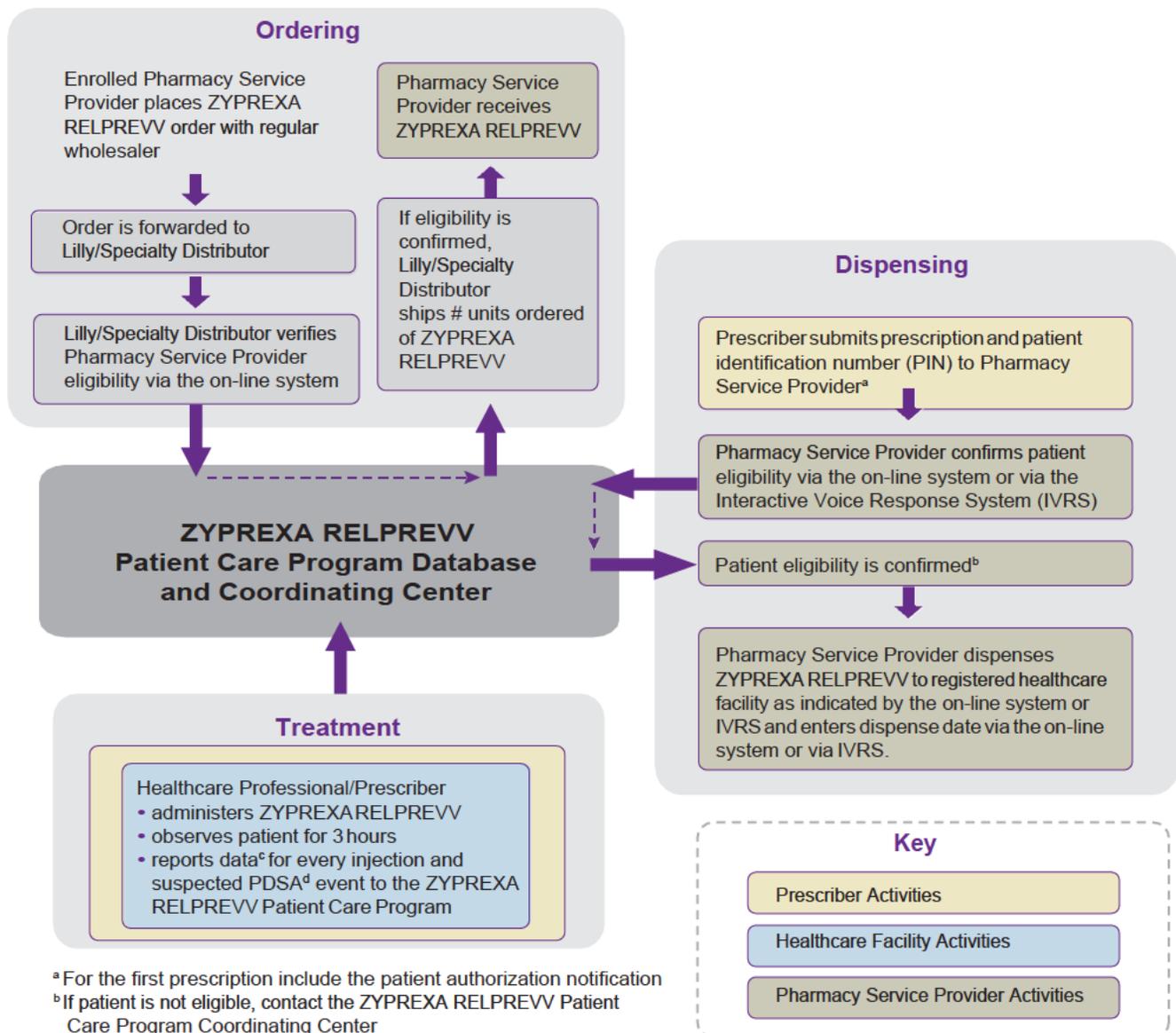
To enroll patient, prescriber:

- Reviews risks of ZYPREXA Relprevv with patient
- Obtain signature of patient or legal guardian OR check box if court order of involuntary commitment
- Submits enrollment form to ZYPREXA Relprevv Patient Care Program Coordinating Center
- Receives & stores patient authorization notification

Pharmacy Service Provider

- Reviews ZYPREXA Relprevv Patient Care Program materials
- Ensures pharmacy staff are trained
- Submits enrollment form to ZYPREXA Relprevv Patient Care Program Coordinating Center

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: 8:00am – 8:00pm ET

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

Via Fax: 1-877-772-9391

Via Internet: www.zyprexarelpbevprogram.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

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

The prescriber is responsible for enrolling the **patient** in the ZYPREXA 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 the patient or legal guardian sign the form, or check the box relating to the presence of a court order. If the court order box is checked, provide the expiration date of the court order. Provide the Patient Registration Form-Patient Copy version to the patient or legal guardian.

3. Submit:

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

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

The prescriber should provide the patient's PIN and healthcare facility unique identifier with the first prescription to assist the pharmacy service provider in completing its ZYPREXA 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.

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.zyprexareprevvprogram.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.

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).

Ordering ZYPREXA RELPREVV

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

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

Dispensing ZYPREXA RELPREVV

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

Via Telephone/IVRS: 1-877-772-9390

Via Internet: www.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.

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

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

- Enter the PIN (If the PIN is not provided, call the Coordinating Center and provide patient's first and last name, patient's date of birth and prescriber's name).
- IVRS provides first 5 letters of prescriber and patient last name
- Confirm both names match prescription
- IVRS provides healthcare facility unique identifier
- Confirm unique identifier/healthcare facility name matches patient authorization notification
- The system will indicate the patient's eligibility to receive ZYPREXA RELPREVV.
- If eligible, the pharmacist will enter the date of dispensing (**prior to** the vial kit leaving the pharmacy) into the Patient Care Program system and dispense only to the healthcare facility (representative) associated with that patient. Do NOT dispense directly to a patient.
- If ineligible, do NOT dispense product. Contact the Patient Care Program Coordinating Center for resolution.

Pharmacy Service Provider Information

Call the Coordinating Center Help Desk 1-877-772-9390

- Provide the PIN (If the PIN is not available, provide patient's first and last name, patient's date of birth and prescriber's name).
- Patient Care Program representative will ask pharmacy provider questions and provides verification of patient eligibility to receive ZYPREXA RELPREVV.
 - If eligible, Patient Care Program representative will enter the date of dispensing **prior to** the vial kit leaving the pharmacy.
 - Pharmacy Service Provider agrees to dispense only to the healthcare facility (representative) associated with that patient and not directly to a patient.
 - If ineligible, Do NOT dispense product. The Coordinating Center will work to resolve.

Product Replacement

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

Reconciliation

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

Glossary of Terms

Healthcare Facility

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

Interactive Voice Response System (IVRS)

System that allows a pharmacy service provider to confirm patient and prescriber eligibility and provide dispensing data via telephone rather than the on-line system.

Patient Authorization Notification

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

Patient Identification Numbers (PIN)

Unique numbers assigned to patients, which are used by the pharmacy service provider to confirm enrollment in the ZYPREXA RELPREVV Patient Care Program.

Pharmacy Service Provider

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

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

Post-Injection Delirium/Sedation Syndrome (PDSS)

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

Prescriber

A healthcare professional writing prescriptions for ZYPREXA RELPREVV. Prescribers are responsible for ensuring that all patients receiving ZYPREXA RELPREVV are enrolled in the program.

BUY & BILL* PHARMACY SERVICE PROVIDER REGISTRATION FORM

BUY & BILL
PHARMACY



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

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

PHARMACY SERVICE PROVIDER INFORMATION

Enrollment Reenrollment

Facility Name: _____

DEA Number: _____

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

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Primary Phone: _____ Secondary Phone: _____

Fax: _____

SHIP TO INFORMATION

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

Ship To Contact Name: _____

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Primary Phone: _____ Secondary Phone: _____

Fax: _____

ADMINISTRATOR INFORMATION

First Name: _____ MI: _____ Last Name: _____

Preferred Method of Communication: Email Fax

Email: _____

Phone: _____ Fax: _____

(If different from above)

(If different from above)

PHARMACY SERVICE PROVIDER AGREEMENT

By signing below, I acknowledge that:

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

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

Administrator Signature

Date: - -

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

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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: _____

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

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

AUTHORIZED HEALTHCARE FACILITY REPRESENTATIVE INFORMATION

First Name: _____ MI: _____ Last Name: _____

Position/Title: _____

Phone: _____ Fax: _____

Email: _____

Preferred Method of Communication: Email Fax

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

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

Facility Name: _____

Phone: _____ Fax: _____
(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: _____

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 Patient Care Program Coordinating Center.

PHONE 1-877-772-9390

FAX 1-877-772-9391

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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 or the patient's legal guardian prior to each injection;
- I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours;
- I will ensure that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVV Patient Care Program.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the health care setting to clarify information provided or to obtain information about the patient.

I confirm that the information above is correct.

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

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

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

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

Authorized Healthcare Facility Representative Signature

Date:

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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.



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"/> Not applicable, patient did not leave facility (in-patient)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable, patient did not leave facility (in-patient)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable, patient did not leave facility (in-patient)
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)
Was the patient or legal guardian given a Medication Guide prior to this injection?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

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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



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.

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

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

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

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

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

Signature Date:

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month day year

Printed Name of Patient

Printed Name of Legal Guardian (if applicable)

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

Date of Court Order Expiration (MMDDYYYY) _____

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

Signature of Prescriber Date:

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month day year

Printed Name of Prescriber

PHONE 1-877-772-9390

FAX 1-877-772-9391

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POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM



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

Patient No (PIN)

Patient Name: _____
 First Name _____ MI _____ Last Name _____

Date of Birth: - -
 month day year

Does the patient have a diagnosis of schizophrenia? Yes No

PATIENT/INJECTION INFORMATION

Date of Injection: - -
month day year

Convenience Kit Package

Lot # _____

Time of ZYPREXA RELPREVV Injection: :
24-hour clock

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

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

Phone 1-877-772-9390

FAX 1-877-772-9391

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POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.:
 (PIN)

Patient Name: _____
 First Name MI Last Name

PDSS start date: - -
 month day year

PDSS resolution date: - - 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)

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POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.:

Patient Name: _____
First Name MI Last Name

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

- | | | | |
|---|------------------------------------|---|--|
| <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: _____

PRESCRIBER REGISTRATION FORM

PRESCRIBER



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

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

PRESCRIBER INFORMATION

Enrollment Reenrollment

First Name: _____ MI: _____ Last Name: _____

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

License Number: _____ State of Issue: _____

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

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

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Phone: _____ Alternate Phone: _____

Fax: _____ Prescriber Email: _____

Preferred Method of Communication: Email Fax

PRESCRIBER AGREEMENT

By signing below, I acknowledge that:

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

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

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

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

Prescriber Signature

Date:

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month day year

PHONE 1-877-772-9390

FAX 1-877-772-9391

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SINGLE PATIENT INJECTION FORM

INJECTION



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

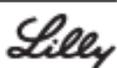
Following the injection, was the patient accompanied from the facility?

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

Was the patient or legal guardian given a Medication Guide prior to this injection? Yes No

Healthcare Facility Staff Member Signature _____ DATE: - -
 month day year

Healthcare Facility Staff Member Name (print): _____



Insert current US Prescribing Information, including the Medication Guide

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 Other with prescriptive authority

License Number: _____ State of Issue: _____

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

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

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Phone: _____ Alternate Phone: _____

Fax: _____ Prescriber Email: _____

Preferred Method of Communication: Email Fax

PRESCRIBER AGREEMENT

By signing below, I acknowledge that:

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

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

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

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

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: _____

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

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Primary Phone: _____ Secondary Phone: _____

Fax: _____

SHIP TO INFORMATION

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

Ship To Contact Name: _____

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Primary Phone: _____ Secondary Phone: _____

Fax: _____

PHARMACIST-IN-CHARGE INFORMATION

First Name: _____ MI: _____ Last Name: _____

Email: _____

Phone: _____ Fax: _____

(if different from above)

(if different from above)

PHARMACIST-IN-CHARGE INFORMATION

By signing below, I acknowledge that:

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



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

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

PHARMACY SERVICE PROVIDER INFORMATION

Enrollment Reenrollment

Facility Name: _____

DEA Number: _____

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

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Primary Phone: _____ Secondary Phone: _____

Fax: _____

SHIP TO INFORMATION

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

Ship To Contact Name: _____

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Primary Phone: _____ Secondary Phone: _____

Fax: _____

ADMINISTRATOR INFORMATION

First Name: _____ MI: _____ Last Name: _____

Preferred Method of Communication: Email Fax

Email: _____

Phone: _____ Fax: _____

(if different from above)

(if different from above)

PHARMACY SERVICE PROVIDER AGREEMENT

By signing below, I acknowledge that:

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

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

Administrator Signature _____ Date:

month		day		year	

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

PHONE 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com

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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: _____

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

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

AUTHORIZED HEALTHCARE FACILITY REPRESENTATIVE INFORMATION

First Name: _____ MI: _____ Last Name: _____

Position/Title: _____

Phone: _____ Fax: _____

Email: _____

Preferred Method of Communication: Email Fax

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

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

Facility Name: _____

Phone: _____ Fax: _____
(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: _____

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 the Patient Care Program Coordinating Center.

PHONE 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com



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 or the patient's legal guardian prior to each injection;
- I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours;
- I will ensure that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVV Patient Care Program.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the health care setting to clarify information provided or to obtain information about the patient.

I confirm that the information above is correct.

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

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

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

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

Authorized Healthcare Facility Representative Signature

Date:

<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			

Authorized Healthcare Facility Representative Name (print) _____ Title _____

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

PHONE 1-877-772-9390

FAX 1-877-772-9391

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Title: ZYPREXA RELPREVV Reconstitution and Administration Training Video

DVD Menu: (Note: the menu only appears on the DVD copies of this video. The digital version used on www.zyprexarelpvprogram.com is a continuous streaming video and cannot be viewed in chapters. This is consistent with the previously approved version of this video.)

ZYPREXA RELPREVV
Reconstitution and Administration Training Video

zyprexaRelprevv
(olanzapine) For Extended Release
Injectable Suspension

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

ZYPREXA RELPREVV[®] is a registered trademark of Eli Lilly and Company.
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Lilly

VIDEO	AUDIO
Introduction	
<p>Text on-screen: ZYPREXA RELPREVV logo</p> <p>ZYPREXA RELPREVV Reconstitution and Administration Training</p>	<i>Music</i>
<p>Text on-screen: ZYPREXA RELPREVV logo Chapter One: Introduction</p>	<i>Music</i>
<p>Text on-screen: ZYPREXA RELPREVV (olanzapine) For Extended Release Injectable Suspension is an antipsychotic agent indicated for the treatment of schizophrenia in adults.</p>	<i>Music</i>
<p>Text on-Screen: 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 full prescribing information provided.</p>	All healthcare professionals who administer this product must view this video before giving an injection of ZYPREXA RELPREVV.
<p>Visual: Nurse (talent) talking to camera</p>	ZYPREXA RELPREVV is a long acting injectable formulation of olanzapine. It is indicated for the 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>Text on-Screen: Vial Strengths: • 210-mg, 300-mg, and 405-mg</p> <p>Dosing Schedules: • Every 2 weeks: 150-mg, 210-mg, or 300-mg • Every 4 weeks: 300-mg or 405-mg</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>Visual: Nurse talking to camera</p>	The purpose of this video is to teach you how to properly reconstitute and administer ZYPREXA RELPREVV.
<p>Text on-Screen:</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>First we will begin by explaining the Post-Injection Delirium/Sedation Syndrome events that occurred with ZYPREXA RELPREVV in pre-marketing clinical trials.</p> <p>Then, we will demonstrate step-by-step instructions on how to properly reconstitute the product.</p> <p>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>Visual: Nurse talking to camera</p>	<p>Please watch the end of this video and see accompanying full prescribing information for important safety information including boxed warnings.</p>								
<p>Post-Injection Delirium/Sedation Syndrome</p>									
<p>Text on-screen: ZYPREXA RELPREVV logo</p> <p>Chapter Two: Post-Injection Delirium/Sedation Syndrome</p>	<p><i>Music</i></p>								
<p>Visual: Nurse talking to camera</p>	<p>During pre-marketing clinical studies, events that presented with signs and symptoms consistent with olanzapine overdose were reported in some patients following an injection of ZYPREXA RELPREVV.</p>								
<p>Text on screen: Events occurred:</p> <ul style="list-style-type: none"> • in < 0.1% of injections • in approximately 2% of patients 	<p>These events occurred in <0.1% of injections and in approximately 2% of patients who received injections for up to 46 months.</p>								
<p>Text on screen: Symptoms:</p> <ul style="list-style-type: none"> • Sedation: ranging from mild in severity up to coma • Delirium: confusion, disorientation, agitation, anxiety, other cognitive impairment • Other Symptoms: extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension, possible convulsion 	<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 included extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension or possible convulsion.</p>								
<p>Text on screen: PDSS Symptom Onset:</p> <table border="1" data-bbox="191 1115 557 1318"> <thead> <tr> <th style="background-color: #8B4513; color: white;">Time of Onset of Symptoms</th> <th style="background-color: #8B4513; color: white;">Patients</th> </tr> </thead> <tbody> <tr> <td><60 min</td> <td>~ 80%</td> </tr> <tr> <td>1 to 3 hours</td> <td>~ 14%</td> </tr> <tr> <td>>3 hours</td> <td>~ 6%</td> </tr> </tbody> </table>	Time of Onset of Symptoms	Patients	<60 min	~ 80%	1 to 3 hours	~ 14%	>3 hours	~ 6%	<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.</p>
Time of Onset of Symptoms	Patients								
<60 min	~ 80%								
1 to 3 hours	~ 14%								
>3 hours	~ 6%								
<p>Visual: Nurse talking to camera</p> <p>Text on screen:</p> <ul style="list-style-type: none"> • Observe patients for 3 hours for symptoms of PDSS 	<p>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. 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>Text on screen: If parenteral benzodiazepines are required for patient management during a PDSS event, careful evaluation of clinical status for excessive sedation and cardiorespiratory depression is recommended.</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>Text on screen: Notify hospital or ER personnel of:</p> <ul style="list-style-type: none"> • "...a probable olanzapine overdose following administration of Olanzapine For Extended Release Injectable Suspension." 	<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>Text on screen: Important: Before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection.</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>
<p>Text on-Screen: After each 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>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>Text on-Screen: 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 to be able to obtain assistance if needed • All patients should be accompanied to their next destination upon leaving the facility 	<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>Text on-Screen: After patient leaves the healthcare facility:</p> <ul style="list-style-type: none"> • Patients should not drive or operate heavy machinery for the remainder of the day 	<p>After leaving the healthcare facility, patients should not drive or operate heavy machinery for the remainder of the day.</p>
<p>Visual: Nurse talking to camera</p>	<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>Text on-Screen: Increased contact with blood can occur:</p> <ul style="list-style-type: none"> • Partial injection into vasculature • Significant vessel injury during IM injection (nick or puncture) • Substantial bleeding at injection site 	<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>Text on-Screen: Deep intramuscular gluteal injection:</p> <ul style="list-style-type: none"> • Intended for deep muscular gluteal injection only <ul style="list-style-type: none"> ○ Not for intravenous, subcutaneous, or deltoid injection • Aspirate syringe prior to injection to ensure no blood is visible • If blood is visible, discard the syringe and use a new product kit 	<p>Therefore, ZYPREXA RELPREVV is intended for deep intramuscular gluteal injection only. It is important to aspirate the syringe prior to injection to ensure no blood is visible. Administrators must not proceed with the injection if blood is visible. If blood is visible, discard the syringe and use a new product kit.</p>
<p>Visual: Nurse talking to camera</p> <p>Text on screen:</p> <ul style="list-style-type: none"> • Post-Injection Delirium/Sedation Syndrome can occur at any injection 	<p>Post-injection Delirium/Sedation Syndrome can occur at any injection, so safety precautions should be observed every time the product is administered.</p>
<p>Step 1 – Prepare Materials</p>	
<p>Text on screen: ZYPREXA RELPREVV logo</p> <p>Chapter Three Step 1 – Prepare Materials</p>	<p>Music</p>
<p>Visual: Nurse talking to camera</p>	<p>Let's begin by preparing for the ZYPREXA RELPREVV injection.</p>
<p>Visual: Pair of hands placing gloves and alcohol wipes on counter.</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>Visual: Nurse talking to camera</p>	<p>The medication comes packaged in a convenience kit that includes the following items:</p>
<p>Visual: Pair of hands placing contents of kit (vial of powder, vial of diluent, Needle-Pro® 3ml syringe with safety needle, 2 additional safety needles) on counter.</p>	<p>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>Visual: Nurse talking to camera</p>	<p>Open the kit, remove all items, and arrange them conveniently to prepare for reconstitution</p>
<p>Visual: Pair of hands putting on gloves</p>	<p>You will need to wear gloves when reconstituting ZYPREXA RELPREVV, as the medication can be irritating to the skin.</p>
<p>Visual: Nurse talking to camera</p>	<p>If the medication contacts skin, flush it with water.</p>

Step 2 – Determine Reconstitution Volume	
<p>Text on screen: ZYPREXA RELPREVV logo</p> <p>Chapter Four Step 2 – Determine Reconstitution Volume</p>	Music
<p>Visual: Nurse talking to camera</p>	Next you will need to determine the reconstitution volume.
<p>Visual: C/U of table on reconstitution and administration instructions</p>	Please refer to the table in the full-color reconstitution and administration instructions for the proper volumes of diluent to add for each vial strength. For example, if you are preparing a 210mg dose, you will need to add 1.3ml of diluent to the 210mg powder vial.
<p>Visual: Nurse talking to camera</p> <p>Text on-screen: There will be excess diluent remaining in the vial</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.
Reconstitute	
<p>Text on screen: ZYPREXA RELPREVV logo</p> <p>Chapter Five Reconstitute</p>	Music
<p>Visual: Nurse talking to camera</p>	Now you are ready to reconstitute ZYPREXA RELPREVV. The process of reconstitution and administration should take around 5 minutes to complete.
<p>Visual: Hands tapping powder vial and wiping vials with alcohol wipes</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>Visual: Hands withdrawing diluent into syringe</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>Visual: Hands injecting diluent into powder vial</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. Hold the vial upright when removing the needle to prevent any loss of medication. Next, engage the safety needle and push the air out of the syringe.
<p>Visual: Hands tapping the vial</p> <p>Text on screen: • Tap firmly and repeatedly</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>Visual: Hands tap and shake vial</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.

<p>Visual: C/U of suspension</p>	<p>If clumps are visible, tap the vial again to break the clumps free. Shake the vial vigorously until the suspension appears smooth and consistent in color and texture.</p>
<p>Visual: Hands continue to shake, tap and inspect vial</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>Visual: Nurse talking to camera</p> <p>Text on screen: Product is stable in the vial for 24 hours after reconstitution.</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 shaken to resuspend before being drawn into the syringe for administration. Once drawn up into the syringe, this medication should be injected immediately.</p>
<p>Inject ZYPREXA RELPREVV</p>	
<p>Text on screen: ZYPREXA RELPREVV logo</p> <p>Chapter Six Inject ZYPREXA RELPREVV</p>	<p><i>Music</i></p>
<p>Visual: Hands attaching new safety needle</p>	<p>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>Visual: C/U of table of instructions</p>	<p>When preparing to draw up the prescribed dose, refer to the table in the instructions for the correct injection volume.</p> <p>For a prescribed dose of 210mg, you will withdraw 1.4ml from the reconstituted vial.</p>
<p>Visual: C/U of hands withdrawing suspension into the syringe</p>	<p>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.</p>
<p>Visual: Nurse talking to camera</p> <p>Text on screen: There will be excess medication remaining in the vial</p>	<p>There will be excess medication remaining in the vial.</p>
<p>Visual: Hands tapping syringe</p>	<p>To ensure the full dose is given, tap the syringe with your fingers to remove all excess air bubbles.</p>
<p>Visual: Hands removing needle from vial, engaging safety device, and attaching new safety needle</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>

<p>Text on screen: Important: Prior to administration, you must make sure that the patient receiving ZYPREXA RELPREVV will be accompanied to his or her destination following the 3-hour observation period.</p> <p>If this cannot be confirmed, do not give the injection.</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.</p>
<p>Text on screen: Important: The patient may not drive to his or her destination for the rest of the day.</p>	<p>Even if accompanied, the patient may not drive to his or her destination or for the rest of the day of injection.</p>
<p>Visual: C/U of syringe</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>Visual: Nurse talking to camera</p> <p>Text On-Screen: Do not inject the medication intravenously or subcutaneously</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 are clinically appropriate sites for deep gluteal injections.</p>
<p>Visual: C/U of anatomical model and hands giving injection</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>
Ventrogluteal Injection	
<p>Text on screen: ZYPREXA RELPREVV logo</p> <p>Chapter Seven Ventrogluteal Injection</p>	<p><i>Music</i></p>
<p>Visual: C/U of practice ventrogluteal injection process on anatomical model</p>	<p>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.</p>
<p>Visual: Nurse talking to camera</p>	<p>If any blood is drawn into the syringe, discard the syringe and the dose, and begin with a new kit.</p>
<p>Visual: C/U on hands giving injection</p>	<p>In this case, no blood is seen, so we will inject the medication with steady pressure.</p>

Visual: C/U of hands withdrawing needle and engaging safety device	After withdrawing the needle carefully from the muscle, engage the needle safety device.
Visual: Nurse talking to camera	Do not massage the injection site
Visual: C/U of hands disposing vial, needle, and syringe	Finally, after the injection, make sure to dispose of the vials, needles, and syringe appropriately.
Dorsogluteal Injection	
Text on-screen: ZYPREXA RELPREVV logo Chapter Eight Dorsogluteal Injection	
Visual: C/U of practice dorsogluteal injection process on anatomical model	To administer a dorsogluteal injection, first locate the upper quadrant of the buttocks by drawing an imaginary line across and down, dividing the buttocks into 4 quadrants. Insert the needle into the gluteal muscle, then aspirate slowly for several seconds by pulling back on the plunger of the syringe. If any blood is drawn into the syringe, discard the syringe and the dose, and begin with a new kit. In this case, no blood is seen, so we will inject the medication with a steady pressure.
Visual: C/U of hands withdrawing needle and engaging safety device	After withdrawing the needle carefully from the gluteal muscle, engage the needle safety device
Visual: Nurse talking to camera Text on-screen: Do not massage the area after the injection	Do not massage the injection site.
Visual: C/U of hands disposing vial, needle, and syringe Text on-screen: Note: The vial is for single use only	Finally, after the injection, make sure to dispose of the vials, needles, and syringe appropriately.
Recap	
Text on-screen: ZYPREXA RELPREVV logo Chapter Nine Recap	<i>Music</i>
Visual: Nurse talking to camera	To summarize, the process of reconstituting and administering ZYPREXA RELPREVV can be broken down into four easy steps.

<p>Text on-screen:</p> <ul style="list-style-type: none"> • Prepare Materials • Determine Reconstitution Volume • Reconstitute • Inject 	<p>One, prepare materials; two, determine reconstitution volume; three, reconstitute; and four, inject.</p>
<p>Visual: Nurse talking to camera</p>	<p>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.</p>
<p>Visual: Real-time reconstitution process with timer</p>	<p><i>Music</i></p>
<p>Text on Screen: 1-800-LillyRx (1-800-545-5979) www.ZyprexaRelprevv.com</p>	<p>If you have any questions about reconstituting and administering ZYPREXA RELPREVV please contact the number on-screen or visit the following website.</p>

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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: _____

PHONE 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com

Version 2.0 03Aug2012

CONFIDENTIAL

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PATIENT AGREEMENT

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

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

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

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

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

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

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

Signature

Date: [] [] - [] [] - [] [] [] []
month day year

Printed Name of Patient

Printed Name of Legal Guardian (if applicable)

Check the box if the patient has not signed due to enrollment decision being made by prescriber who is authorized via a court order.
Date of Court Order Expiration (MMDDYYYY) _____

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

Signature of Prescriber

Date: [] [] - [] [] - [] [] [] []
month day year

Printed Name of Prescriber

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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 Not applicable, patient did not leave facility (in-patient)

Was the patient or legal guardian given a Medication Guide prior to this injection? Yes No

Healthcare Facility Staff Member Signature _____ DATE: - -
 month day year

Healthcare Facility Staff Member Name (print): _____



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:	mon h - 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"/>
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"/> Not applicable, patient did not leave facility (in-patient)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable, patient did not leave facility (in-patient)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable, patient did not leave facility (in-patient)
Signature	Healthcare Facility Staff Member Signature _____ <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"/> month day year Healthcare Facility Staff Member Name (print)	Healthcare Facility Staff Member Signature _____ <input type="text"/> - <input type="text"/> - <input type="text"/> month day year Healthcare Facility Staff Member Name (print)
Was the patient or legal guardian given a Medication Guide prior to this injection?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No



POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM



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

Patient No.: (PIN)

Patient Name: _____
First Name MI Last Name

Date of Birth: - -
month day year

Does the patient have a diagnosis of schizophrenia? Yes No

PATIENT/INJECTION INFORMATION

Date of Injection: - -
month day year

Convenience Kit Package

Lot # _____

Time of ZYPREXA RELPREVV Injection: :
24-hour clock

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 _____ |

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POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.: (PIN)

Patient Name: _____
First Name MI Last Name

PDSS start date: - -
month day year

PDSS resolution date: - - 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.:

(PIN)

Patient Name: _____
 First Name MI Last Name

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

- | | | | |
|---|------------------------------------|---|--|
| <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: _____



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](#).

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[Prescribing Information](#)

[Log In](#)

[Registration Forms](#)

[Medication Guide](#)

[Contact Us](#)

[Order Educational Materials](#)

[Pharmacy Finder](#)

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

This site is intended for U.S. residents age 18 and over.

For more information about ZYPREXA RELPREVV, contact your doctor or other healthcare professional.

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[Terms Of Use](#)

zyprexaRelprevv
(olanzapine) For Extended Release
Injectable Suspension

Welcome to the ZYPREXA RELPREVV Patient Care Program

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[Registration Forms](#)

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Please see Prescribing Information for full details about the ZYPREXA RELPREVV Patient Care Program. This site is intended for U.S. residents age 18 and over. For more information about ZYPREXA RELPREVV, contact [our customer support](#).

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https://training.zyprexa.com

training.zyprexa.com

File Edit Go to Favorites Help

AIM Reimbursement-PAP ... Amgen NBU - Home Approved Risk Evaluation ... Backlog items

ZYPREXA RELPREVV Patient Care Program

Getting started with the Zyprexa Relprevv Patient Care Program and the 3 steps to enrollment.

zyprexaRelprevv
(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](#) **1** [Prescribing Information](#) [Log In](#) **3**

[Registration Forms](#) **2** [Medication Guide](#) [Contact Us](#)

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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[TERMS OF USE](#)

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

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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

ZYPREXA RELPREVV Patient Care Program Instructions Brochure

Required Prescriber Training

- ZYPREXA RELPREVV Pa**
- Healthcare Professional T
 - Slide Presentation**

OR

- Recorded Presentation**

ADDITIONAL RESOURCES

Post-Injection Delirium/Sedation Syr

Once you have completed the required tra

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ZYPREXA RELPREVV Patient Care Program

Required Prescriber Training

1. **ZYPREXA RELPREVV**
 2. Healthcare Professional
 - **Slide Presentation**
- OR
- **Recorded Presentation**

ADDITIONAL RESOURCES

Post-Injection Delirium/Sedation

Once you have completed the require

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Training Presentation

ZYPREXA RELPREVV
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Injectable Suspension

Training for Healthcare Professionals

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

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ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

The goal of this presentation is to educate healthcare professionals in an effort to mitigate negative outcomes associated with ZYPREXA RELPREVV post-injection delirium/sedation syndrome (PDSS). Healthcare professionals include: physicians, nurses and any other professionals who will be involved with the care of the patient receiving the injection.

Please see the Prescribing Information and the Reconstitution and Administration Poster



ZYPREXA RELPREVV Patient Care Program

Required Prescriber Training

1. **ZYPREXA RELPREVV P**
 2. Healthcare Professional T
- **Slide Presentation**
- OR
- **Recorded Presentation**

ADDITIONAL RESOURCES

[Post-Injection Delirium/Sedation Syndrome Case](#)

Once you have completed the required training, submit

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Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVV.

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HCP_ROM - Internet Explorer
https://zyprexa.dev.ubcpsc.com/public/home.htm



ZYPREXA[®] RELPREVV[™]
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Training for Healthcare Professionals

Please see the Prescribing Information and the Reconstitution and Administration Poster before using ZYPREXA[®] RELPREVV[™]

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Required Prescriber Training

Post-Injection Delirium/Sedation Syndrome Case Study Video

ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension
210 mg/vial, 300 mg/vial, and 405 mg/vial

Post-Injection Delirium/Sedation Syndrome Case Study Video

00:00:07 / 00:39:19

ADDITIONAL

Post-Injection

Once you

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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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(olanzapine) For Extended Release
Injectable Suspension

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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

Training Presentation

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

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Injectable Suspension*

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

The goal of this presentation is to educate healthcare professionals in an effort to mitigate negative outcomes associated with ZYPREXA RELPREVV post-injection delirium/sedation syndrome (PDSS). Healthcare professionals include: physicians, nurses and any other professionals who will be involved with the care of the patient receiving the injection.

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

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ZYPREXA RELPREVV Patient Care Program

Required Healthcare Facility Staff Training

The screenshot shows a web browser window with the following elements:

- Address Bar:** Contains the URL <https://training.zyprexa...> and a tab titled "training.zyprexarelprevvpro...".
- Page Header:** A dark blue banner with the text "ZYPREXA RELPREVV Patient Care Program Instructions Brochure".
- Main Content:** The ZYPREXA RELPREVV logo, with "ZYPREXA" in blue and "Relprevv" in red. Below the logo, the text "(olanzapine) For Extended Release Injectable Suspension" is displayed.
- Footer:** On the left side, there is a "PRIVACY" link and a "Please Read This For" notice. At the bottom left, there is a copyright notice: "©Lilly U.S. VERSON Site hc".

ZYPREXA RELPREVV Patient Care Program

Required Healthcare Facility Staff Training

- **REQUIRED TRAINING FOR STAFF ADMINISTERING INJECTIONS AND STAFF WHO MONITOR PATIENTS**

1. 
2. 
3. 

ADDI

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

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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)

Instructions to Reconstitute and Administer ZYPREXA RELPREVV

FOR DEEP INTRAMUSCULAR GLUTEAL INJECTION ONLY. NOT TO BE INJECTED INTRAVENOUSLY OR SUBCUTANEOUSLY.

For Important Safety Information, including boxed warnings, see the full Prescribing Information provided.

STEP 1 PREPARING MATERIALS

Convenience kit includes:
(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® needle with needle protection device
- Two 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needles with needle protection device.
 - For obese patients, a 2-inch (50 mm), 19-gauge or larger needle (not included in convenience kit) may be used for administration.

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

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

STEP 2 DETERMINING RECONSTITUTION VOLUME

Dose	Vial Strength	Diluent to Add
150 mg	210 mg	1.5 mL
210 mg	210 mg	1.5 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

- 3.1 Loosen the powder by lightly tapping the vial.
- 3.2 Open the prepackaged Hypodermic Needle-Pro syringe and needle with needle protection device.
- 3.3 Withdraw the pre-determined diluent volume (Step 2) into the syringe.

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ZYPREXA RELPREVV Patient Care Program

Required Healthcare Facility Staff Training

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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Injectable Suspension

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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

Required Pharmacy Service Provider Training

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- Address Bar:** <https://training.zyprexa...>
- Page Title:** ZYPREXA RELPREVV Patient Care Program Instructions Brochure
- Main Content:**

ZYPREXA[®]Relprevv[™]
*(olanzapine) For Extended Release
Injectable Suspension*
- Footer (Left Side):**

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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](#)

- *[Patient Copy](#)*

[Healthcare Facility Registration Form](#)

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ZYPREXA RELPREVV Patient Care Program

Registration Forms

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[Prescriber Registration Form](#)

[Pharmacy Registration Form](#)

[Buy & Bill Pharmacy Service Provider Registration Form](#)

[Patient Registration Form](#)

- [Patient Copy](#)

[Healthcare Facility Registration Form](#)

Registration Type

Do you want to complete your registration on-line or print a registration form?

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ZYPREXA RELPREVV Patient Care Program

PRESCRIBER REGISTRATION FORM

PRESCRIBER REGISTRATION FORM

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Injectable Suspension

To be enrolled in the ZYPREXA RELPREVV Patient Care Program, complete this form.
Training must be completed before a prescriber may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

PRESCRIBER INFORMATION

Enrollment Reenrollment

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

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

License Number: **State of Issue:**

Treatment Facility/Practice (where you see your patients):
If you see your patients at multiple locations please contact the ZYPREXA RELPREVV Patient Care Program Coordinating Center to provide additional facility/practice information

Address Line 1:

Address Line 2:

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

Phone: **Alternate Phone:**

Fax: **Prescriber Email:**

Preferred Method of Communication: Email Fax

PRESCRIBER AGREEMENT

By signing below, I acknowledge that:
 I understand the ZYPREXA RELPREVV Patient Care Program requirements and the risks associated with ZYPREXA RELPREVV.

/registration/SelfRegister.aspx?TID=3

ZYPREXA RELPREVV Patient Care Program

PRESCRIBER REGISTRATION FORM

By signing below, I acknowledge that:

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

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

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

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

- I, attest that I am the Prescriber, and understand that by clicking submit the information provided on this form is true and accurate.

State License Number:

Submit

Cancel

Phone 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelpvprogram.com

/registration/SelfRegister.aspx?TID=3

ZYPREXA RELPREVV Patient Care Program

PRESCRIBER REGISTRATION FORM

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;
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- I will review the ZYPREXA RELPREVV Medication Guide with each patient prior to prescribing.
- I understand that the ZYPREXA RELPREVV Patient Care Program requires me to report any discrepancies, to obtain information about a patient, or to conduct occasional surveys.

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State License Number:

Submit

Cancel

Phone 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com

/registration/SelfRegister.aspx?TID=3

Confirm Close Window



Enrollment data will not be retained if you leave the enrollment process without submission.

OK

Cancel

ZYPREXA RELPREVV Patient Care Program

75% Collaborate Sign 1 / 1

PRESCRIBER REGISTRATION FORM

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*(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 prescriber may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

PRESCRIBER INFORMATION

Enrollment Reenrollment

First Name: _____ MI: _____ Last Name: _____

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

License Number: _____ State of Issue: _____

Treatment Facility/Practice (Where you see your patients): _____
If you see your patients at multiple locations please contact the ZYPREXA RELPREVV Patient Care Program Coordinating Center to provide additional facility/practice information

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Phone: _____ Alternate Phone: _____

Fax: _____ Prescriber Email: _____

Preferred Method of Communication: Email Fax

PRESCRIBER AGREEMENT

By signing below, I acknowledge that:

- I understand the ZYPREXA RELPREVV Patient Care Program requirements and the risks associated with ZYPREXA RELPREVV.
- I have completed the mandatory ZYPREXA RELPREVV training.
- I understand the clinical presentation of post-injection delirium/sedation syndrome (PDSS) and how to manage patients should an event occur while using ZYPREXA RELPREVV;
- I understand that ZYPREXA RELPREVV should only be initiated in patients for whom tolerability with oral olanzapine has been established;

ZYPREXA RELPREVV Patient Care Program

Phone: _____ Prescriber 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.

Date: - -
month day year

Prescriber Signature

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

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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](#)

[Patient Registration Form](#)

- [Patient Copy](#)

[Healthcare Facility Registration Form](#)

Registration Type

Do you want to complete your registration on-line or print a registration form?

[PRIVACY POLICY](#)

[TERMS OF USE](#)

ZYPREXA RELPREVV
(olanzapine) For Extended Release
Injectable Suspension

[Home](#) | [On-line Training](#) | [Registration Forms](#) | [Order Educational Materials](#) | [Prescribing Information](#) | [Medication Guide](#)

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

This site is intended for U.S. residents age 18 and over.

For more information about ZYPREXA RELPREVV, contact your doctor or other healthcare professional.

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Lilly

ZYPREXA RELPREVV Patient Care Program

PHARMACY REGISTRATION FORM

PHARMACY REGISTRATION FORM

zyprexaRelprevv
(olanzapine) For Extended Release
Injectable Suspension

To be enrolled in the ZYPREXA RELPREVV Patient Care Program, complete this form.
Training must be completed before a pharmacy may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

PHARMACY INFORMATION

Enrollment Reenrollment

Pharmacy/Hospital Name:

Pharmacy DEA Number:

Please specify description of Pharmacy:

Community / Retail Specialty Pharmacy Hospital or Institution Other

Address Line 1:

Address Line 2:

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

Primary Phone: **Secondary Phone:**

Fax:

SHIP TO INFORMATION

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

Ship To Contact Name:

Address Line 1:

Address Line 2:

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

/registration/SelfRegister.aspx?TID=2

ZYPREXA RELPREVV Patient Care Program

PHARMACY REGISTRATION FORM

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 AGREEMENT

By signing below, I acknowledge that:

- I have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.
- I will ensure that all appropriate pharmacy staff are trained and have read and understand the ZYPREXA RELPREVV Patient Care Program Instructions Brochure.
- I will ensure that all appropriate pharmacy staff understand that ZYPREXA RELPREVV can only be dispensed for use in certain 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

/registration/SelfRegister.aspx?TID=2

ZYPREXA RELPREVV Patient Care Program

PHARMACY REGISTRATION FORM

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

- I will ensure that pharmacy staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to dispensing each prescription/refill by accessing the system.
- I will ensure that pharmacy staff will not dispense ZYPREXA RELPREVV directly to patients.
- I will ensure pharmacy staff report the date of each ZYPREXA RELPREVV dispensing to the ZYPREXA RELPREVV Patient Care Program.
- For each dispense I will ensure prescription verification (includes patient eligibility check and recording the dispense date) is completed on the date of dispense, prior to the convenience kit leaving the pharmacy.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the pharmacy to clarify information provided or to obtain information about the patient.

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

- I, attest that I am the Pharmacist-In-Charge, and understand that by clicking submit the information provided on this form is true and accurate

Confirm DEA #:

Submit

Cancel

Phone 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com

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ZYPREXA RELPREVV Patient Care Program

PHARMACY REGISTRATION FORM

I hereby ensure that an appropriate pharmacy, clinic, ambulatory care center, or hospital can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services and that can allow for continuous patient monitoring for at least 3 hours post-injection.

- I will ensure that pharmacy staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to dispensing each prescription/refill by accessing the system.
- I will ensure that pharmacy staff will not dispense ZYPREXA RELPREVV directly to patients.
- I will ensure pharmacy staff report the date of each ZYPREXA RELPREVV dispensing to the ZYPREXA RELPREVV Patient Care Program.
- For each dispense I will ensure prescription verification (includes patient eligibility check and recording the dispense date) is completed on the date of dispense, prior to the convenience kit leaving the pharmacy.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the pharmacy to clarify information provided or to obtain information about the patient.

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

I, attest that I am the Pharmacist-In-Charge, and the information provided on this form is true and accurate

Confirm DEA #:

Phone 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com

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Confirm Close Window

Enrollment data will not be retained if you leave the enrollment process without submission.

ZYPREXA RELPREVV Patient Care Program

Collaborate Sign 1 / 1

PHARMACY REGISTRATION FORM

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 may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

PHARMACY INFORMATION

Enrollment Reenrollment

Pharmacy/Hospital Name: _____

Pharmacy DEA Number: _____

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

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Primary Phone: _____ Secondary Phone: _____

Fax: _____

SHIP TO INFORMATION

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

Ship To Contact Name: _____

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Primary Phone: _____ Secondary Phone: _____

Fax: _____

PHARMACIST-IN-CHARGE INFORMATION

First Name: _____ MI: _____ Last Name: _____

Email: _____

PHARMACY

ZYPREXA RELPREVV Patient Care Program

Collaborate Sign 1 / 1

Address Line 1: _____
Address Line 2: _____
City: _____ State: _____ Zip: _____
Primary Phone: _____ Secondary Phone: _____
Fax: _____

PHARMACIST-IN-CHARGE INFORMATION

First Name: _____ MI: _____ Last Name: _____
Email: _____
Phone: _____ Fax: _____
(if different from above) (if different from above)

PHARMACIST-IN-CHARGE INFORMATION

By signing below, I acknowledge that:

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

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

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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](#)

[Patient Registration Form](#)

- [Patient Copy](#)

[Healthcare Facility Registration Form](#)

Registration Type

Do you want to complete your registration on-line or print a registration form?

[PRIVACY POLICY](#)

[TERMS OF USE](#)

ZYPREXA RELPREVV
(olanzapine) For Extended Release
Injectable Suspension

[Home](#) | [On-line Training](#) | [Registration Forms](#) | [Order Educational Materials](#) | [Prescribing Information](#) | [Medication Guide](#)

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

This site is intended for U.S. residents age 18 and over.
For more information about ZYPREXA RELPREVV, contact your doctor or other healthcare professional.

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ZYPREXA RELPREVV Patient Care Program

BUY AND BILL* PHARMACY SERVICE PROVIDER REGISTRATION FORM

BUY AND BILL* PHARMACY SERVICE PROVIDER REGISTRATION FORM



To be enrolled in the ZYPREXA RELPREVV Patient Care Program, complete this form.
Training must be completed before a pharmacy service provider may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

PHARMACY SERVICE PROVIDER INFORMATION

Enrollment Reenrollment

Facility Name:

DEA Number:

Please specify description of Pharmacy:

Community / Retail Specialty Pharmacy Hospital or Institution Other

Address Line 1:

Address Line 2:

City: State: Zip:

Primary Phone: () - - Secondary Phone: () - -

Fax: () - -

SHIP TO INFORMATION

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

Ship To Contact Name:

Address Line 1:

Address Line 2:

City: State: Zip:

/registration/SelfRegister.aspx?TID=4

ZYPREXA RELPREVV Patient Care Program

BUY AND BILL™ PHARMACY SERVICE PROVIDER REGISTRATION FORM

City: State: Zip:
Primary Phone: () - - Secondary Phone: () - -
Fax: () - -

ADMINISTRATOR INFORMATION

First Name: MI: Last Name:
Preferred Method of Communication: Email Fax
Email:
Phone: () - - Fax: () - -
(if different from above) (if different from above)

PHARMACY SERVICE PROVIDER AGREEMENT

By signing below, I acknowledge that:

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

/registration/SelfRegister.aspx?TID=4

ZYPREXA RELPREVV Patient Care Program

BUY AND BILL* PHARMACY SERVICE PROVIDER REGISTRATION FORM

PHARMACY SERVICE PROVIDER AGREEMENT

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

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

I, attest that I am the Administrator, and understand that by clicking submit the information provided on this form is true and accurate.

Confirm DEA #:

Submit

Cancel

*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

/registration/SelfRegister.aspx?TID=4

ZYPREXA RELPREVV Patient Care Program

BUY AND BILL* PHARMACY SERVICE PROVIDER REGISTRATION FORM

PHARMACY SERVICE PROVIDER AGREEMENT

By signing below, I acknowledge that:

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

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

I, attest that I am the Administrator, and understand that by clicking submit the information provided on this form is true and accurate.

Confirm DEA #:

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

Phone 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com

/registration/SelfRegister.aspx?TID=4

Confirm Close Window

Enrollment data will not be retained if you leave the enrollment process without submission.

ZYPREXA RELPREVV Patient Care Program

Collaborate Sign 1 / 1

BUY & BILL* PHARMACY SERVICE PROVIDER REGISTRATION FORM

zypraxaRelprevv
*(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: _____

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

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Primary Phone: _____ Secondary Phone: _____

Fax: _____

SHIP TO INFORMATION

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

Ship To Contact Name: _____

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Primary Phone: _____ Secondary Phone: _____

Fax: _____

ADMINISTRATOR INFORMATION

First Name: _____ MI: _____ Last Name: _____

Preferred Method of Communication: Email Fax

Email: _____

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

PHARMACY SERVICE PROVIDER AGREEMENT

By signing below, I acknowledge that:

BUY & BILL
PHARMACY

ZYPREXA RELPREVV Patient Care Program

Collaborate Sign 1 / 1

SHIP TO INFORMATION

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

Ship To Contact Name: _____

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip: _____

Primary Phone: _____ Secondary Phone: _____

Fax: _____

ADMINISTRATOR INFORMATION

First Name: _____ MI: _____ Last Name: _____

Preferred Method of Communication: Email Fax

Email: _____

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

PHARMACY SERVICE PROVIDER AGREEMENT

By signing below, I acknowledge that:

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

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

Administrator Signature _____ Date: - -

month day year

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

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

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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](#)

[Patient Registration Form](#)

- [Patient Copy](#)

[Healthcare Facility Registration Form](#)

Registration Type

 Patient Registration Forms are available in PDF format for printing.

[Print](#)

[PRIVACY POLICY](#)

[TERMS OF USE](#)

zyprexaRelprevv
(olanzapine) For Extended Release
Injectable Suspension

[Home](#) | [On-line Training](#) | [Registration Forms](#) | [Order Educational Materials](#) | [Prescribing Information](#) | [Medication Guide](#) |

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

This site is intended for U.S. residents age 18 and over.
For more information about ZYPREXA RELPREVV, contact your doctor or other healthcare professional.

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Lilly

75% Collaborate Sign 1 / 2

PATIENT REGISTRATION FORM

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.

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)

PATIENT page 1 of 2

ZYPREXA RELPREVV Patient Care Program

Collaborate Sign 75% 1 / 2

INJECTING/MONITORING FACILITY INFORMATION

Facility Name (where the patient receives injections or monitoring): _____
Address Line 1: _____
Address Line 2: _____
City: _____ State: _____ Zip: _____

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

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:

PATIENT Page 2 of 2

ZYPREXA RELPREVV Patient Care Program

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

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

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

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

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

Signature _____ Date: - -
month day year

Printed Name of Patient _____

ZYPREXA RELPREVV Patient Care Program

Collaborate Sign 2 / 2

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

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

Signature _____ Date: - -
month day year

Printed Name of Patient _____

Printed Name of Legal Guardian (if applicable) _____

Check the box if the patient has not signed due to enrollment decision being made by prescriber who is authorized via a court order.
Date of Court Order Expiration (MMDDYYYY) _____

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

Signature of Prescriber _____ Date: - -
month day year

Printed Name of Prescriber _____

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

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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](#)

[Patient Registration Form](#)

- [Patient Copy](#)

[Healthcare Facility Registration Form](#)

Registration Type

 Patient Registration Forms are available in PDF format for printing.

[Print](#)

[PRIVACY POLICY](#)

[TERMS OF USE](#)

ZYPREXA Relprevv
(olanzapine) For Extended Release
Injectable Suspension

[Home](#) | [On-line Training](#) | [Registration Forms](#) | [Order Educational Materials](#) | [Prescribing Information](#) | [Medication Guide](#) |

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

This site is intended for U.S. residents age 18 and over.
For more information about ZYPREXA RELPREVV, contact your doctor or other healthcare professional.

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ZYPREXA RELPREVV Patient Care Program

Collaborate Sign 1 / 1

PATIENT REGISTRATION FORM COPY

zyprexaRelprevv
(olanzapine) For Extended Release
Injectable Suspension

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.

PATIENT COPY

ZYPREXA RELPREVV Patient Care Program

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.

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ZYPREXA RELPREVV Patient Care Program

Registration Forms

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[Prescriber Registration Form](#)

[Pharmacy Registration Form](#)

[Buy & Bill Pharmacy Service Provider Registration Form](#)

[Patient Registration Form](#)

- [Patient Copy](#)

[Healthcare Facility Registration Form](#)

Registration Type

Do you want to complete your registration on-line or print a registration form?

[PRIVACY POLICY](#)

[TERMS OF USE](#)

ZYPREXA RELPREVV
(olanzapine) For Extended Release
Injectable Suspension

[Home](#) | [On-line Training](#) | [Registration Forms](#) | [Order Educational Materials](#) | [Prescribing Information](#) | [Medication Guide](#)

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

This site is intended for U.S. residents age 18 and over.

For more information about ZYPREXA RELPREVV, contact your doctor or other healthcare professional.

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ZYPREXA RELPREVV Patient Care Program

HEALTHCARE FACILITY REGISTRATION FORM

HEALTHCARE FACILITY REGISTRATION FORM



To be enrolled in the ZYPREXA RELPREVV Patient Care Program, complete this form.
Training must be completed before a healthcare facility may be enrolled in the ZYPREXA RELPREVV Patient Care Program.

HEALTHCARE FACILITY INFORMATION

Enrollment Reenrollment

Healthcare Facility Name:

Please specify location of Healthcare Facilities:

Prescriber Office Clinic / Outpatient Facility Hospital Other

Address:

City: State: Zip:

Phone: Fax:

AUTHORIZED HEALTHCARE FACILITY REPRESENTATIVE INFORMATION

First Name: MI: Last Name:

Position/Title:

Phone: Fax:

Email:

Preferred Method of Communication: Email Fax

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

Delegate First Name: MI: Last Name:

Facility Name:

/registration/SelfRegister.aspx?TID=1

ZYPREXA RELPREVV Patient Care Program

HEALTHCARE FACILITY REGISTRATION FORM

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 AGREEMENT

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

/registration/SelfRegister.aspx?TID=1

ZYPREXA RELPREVV Patient Care Program

HEALTHCARE FACILITY REGISTRATION FORM

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

[/registration/SelfRegister.aspx?TID=1](#)

ZYPREXA RELPREVV Patient Care Program

HEALTHCARE FACILITY REGISTRATION FORM

- I will ensure that appropriate staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to each injection, by accessing the system;
- I will ensure that the Medication Guide is provided to the patient prior to each injection;
- I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours;
- I will ensure that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVV Patient Care Program.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the health care setting to clarify information provided or to obtain information about the patient.

I confirm that the information above is correct.

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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.

I, attest that I am the Healthcare Facility Representative, and understand that by clicking submit the information provided on this form is true and accurate.

**Confirm Facility Phone
Number:**

Submit

Cancel

Phone 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com

/registration/SelfRegister.aspx?TID=1

ZYPREXA RELPREVV Patient Care Program

HEALTHCARE FACILITY REGISTRATION FORM

- I will ensure that appropriate staff will verify that the patient is enrolled in the ZYPREXA RELPREVV Patient Care Program registry prior to each injection, by accessing the system;
- I will ensure that the Medication Guide is provided to the patient prior to each injection;
- I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours;
- I will ensure that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVV Patient Care Program.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the health care setting to clarify information provided or to obtain information about the patient.

I confirm that the information above is correct.

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

I also understand that this information may be shared with

I understand that Lilly will regularly evaluate ZYPREXA RELPREVV program objectives are met. Lilly reserves the right to terminate a healthcare facility's enrollment at any time based on 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.

- I, attest that I am the Healthcare Facility Representative, and understand that by clicking submit the information provided on this form is true and accurate.

Confirm Facility Phone
Number:

Submit

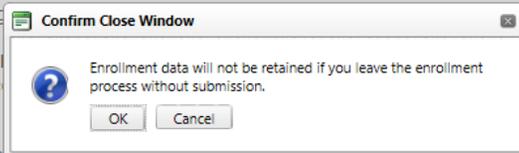
Cancel

Phone 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com

/registration/SelfRegister.aspx?TID=1



ZYPREXA RELPREVV Patient Care Program

Collaborate Sign 1 / 2

HEALTHCARE FACILITY REGISTRATION FORM

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

HEALTHCARE FACILITY INFORMATION

Enrollment Reenrollment

Healthcare Facility Name: _____

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

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

AUTHORIZED HEALTHCARE FACILITY REPRESENTATIVE INFORMATION

First Name: _____ MI: _____ Last Name: _____

Position/Title: _____

Phone: _____ Fax: _____

Email: _____

Preferred Method of Communication: Email Fax

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

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

Facility Name: _____

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

Email: _____

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

Facility Name: _____

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

HEALTHCARE FACILITY Page 1 of 2

ZYPREXA RELPREVV Patient Care Program

Collaborate Sign 1 / 2

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 the Patient Care Program Coordinating Center.

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

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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

HEALTHCARE FACILITY Page 2 of 2

ZYPREXA RELPREVV Patient Care Program

75% Collaborate Sign 2 / 2

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

I confirm that the information above is correct.

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

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

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

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

Date: - -

ZYPREXA RELPREVV Patient Care Program

Collaborate Sign 75% 2 / 2

I will ensure that the medication guide is provided to the patient or the patient's legal guardian prior to each injection.

- I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours;
- I will ensure that required data are submitted within 7 days after each injection to the ZYPREXA RELPREVV Patient Care Program.
- I understand that the ZYPREXA RELPREVV Patient Care Program Coordinating Center may contact the health care setting to clarify information provided or to obtain information about the patient.

I confirm that the information above is correct.

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

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

Authorized Healthcare Facility Representative Signature

Date: - -
month day year

Authorized Healthcare Facility Representative Name (print) Title _____

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

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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.

*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)

Patient Materials

10 Wristbands

10 ID cards

Forms Available as Individual Items

- Single Patient Injection Form - tear-off pad of forms (25 forms/pad)
- Multiple Patient Injection Form - tear-off pad of forms (25 forms/pad)
- PDSS Form - 3 forms/pack
- Patient Registration Form - 5 patient forms/pack

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

I understand that any personal information provided on this form will be used to provide educational materials only. For further privacy information please see the [Privacy Policy](#).

Submit

[PRIVACY POLICY](#)

[TERMS OF USE](#)

zyprexaRelprevv
(olanzapine) For Extended Release
Injectable Suspension

[Home](#) | [On-line Training](#) | [Registration Forms](#) | [Order Educational Materials](#) | [Prescribing Information](#) | [Medication Guide](#) |

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

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For more information about ZYPREXA RELPREVV, contact your doctor or other healthcare professional.

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ZYPREXA RELPREVV Patient Care Program

Prescribing Information

[Prescribing Information](#)

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ZYPREXA RELPREVV Patient Care Program

http://pi.lilly.com/us/zyprex pi.lilly.com

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

WARNING: POST-INJECTION DELIRIUM/SEDATION SYNDROME AND INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
 See full prescribing information for complete boxed warning.

- Patients are at risk for severe sedation (including coma) and/or delirium after each injection and must be observed for at least 3 hours in a registered facility with ready access to emergency response services. Because of this risk, ZYPREXA RELPREVV is available only through a restricted distribution program called ZYPREXA RELPREVV Patient Care Program and requires prescriber, healthcare facility, patient, and pharmacy enrollment. (2.1, 5.1, 5.2, 10.2, 17.2)
- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ZYPREXA RELPREVV is not approved for the treatment of patients with dementia-related psychosis. (5.3, 5.16, 17.3)

RECENT MAJOR CHANGES

Warnings and Precautions:	
Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (5.6)	10/2016
Falls (5.10)	01/2017

INDICATIONS AND USAGE

ZYPREXA[®] RELPREVV[™] is a long-acting atypical antipsychotic for intramuscular injection indicated for the treatment of schizophrenia. (1.1)

Efficacy was established in two clinical trials in patients with schizophrenia: one 8-week trial in adults and one maintenance trial in adults. (14.1)

DOSAGE AND ADMINISTRATION

150 mg/2 wks, 300 mg/4 wks, 210 mg/2 wks, 405 mg/4 wks, or 300 mg/2 wks. See Table 1 for dosing recommendations. (2.1)

ZYPREXA RELPREVV is intended for deep intramuscular gluteal injection only.

- Do not administer intravenously or subcutaneously. (2.1)
- Be aware that there are two ZYPREXA intramuscular formulations with different dosing schedules. ZYPREXA intramuscular (150 mg/2 weeks) and ZYPREXA RELPREVV (150 mg/2 weeks) should not be administered together.

ADVERSE REACTIONS

Most common adverse reactions (≥5% in at least one of the treatment groups and greater than placebo) associated with ZYPREXA

- Suicide: The possibility of a suicide attempt is inherent in schizophrenia, and close supervision of high-risk patients should accompany drug therapy. (5.4)
- Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring. (5.5)
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Discontinue if DRESS is suspected. (5.6)
- Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes including hyperglycemia, dyslipidemia, and weight gain. (5.7)
 - Hyperglycemia and Diabetes Mellitus: In some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients taking olanzapine. Patients taking olanzapine should be monitored for symptoms of hyperglycemia and undergo fasting blood glucose testing at the beginning of, and periodically during, treatment. (5.7)
 - Dyslipidemia: Undesirable alterations in lipids have been observed. Appropriate clinical monitoring is recommended, including fasting blood lipid testing at the beginning of, and periodically during, treatment. (5.7)
 - Weight Gain: Potential consequences of weight gain should be considered. Patients should receive regular monitoring of weight. (5.7)
- Tardive Dyskinesia: Discontinue if clinically appropriate. (5.8)
- Orthostatic Hypotension: Orthostatic hypotension associated with dizziness, tachycardia, bradycardia and, in some patients, syncope, may occur especially during initial dose titration. Use caution in patients with cardiovascular disease, cerebrovascular disease, and those conditions that could affect hemodynamic responses. (5.9)
- Leukopenia, Neutropenia, and Agranulocytosis: Has been reported with antipsychotics, including ZYPREXA. Patients with a history of a clinically significant low white blood cell count (WBC) or drug induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and discontinuation of ZYPREXA RELPREVV should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors. (5.11)
- Seizures: Use cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold. (5.13)
- Potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Use caution when operating machinery. (5.14)
- Hyperprolactinemia: May elevate prolactin levels. (5.17)
- Laboratory Tests: Monitor fasting blood glucose and lipid profiles at the beginning of, and periodically during, treatment. (5.18)

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ZYPREXA RELPREVV Patient Care Program

Medication Guide

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

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http://pi.lilly.com/us/zyprex

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Medication Guide

ZYPREXA® RELPREVV™ (zy-PREX-a REL-prev) (olanzapine) For Extended Release Injectable Suspension

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

What is the most important information I should know about ZYPREXA RELPREVV?
Before you receive ZYPREXA RELPREVV treatment you must:

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

ZYPREXA RELPREVV may cause serious side effects, including:

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

These serious side effects are described below.

1. **Post-injection Delirium Sedation Syndrome (PDSS).** PDSS is a serious problem that can happen after you get a ZYPREXA RELPREVV injection if the medicine gets in your blood too fast. This problem usually happens within 3 hours after you receive ZYPREXA RELPREVV. If the medicine gets in your blood too fast, you may have some of the following symptoms:
 - feel more sleepy than usual
 - feel dizzy
 - feel confused or disoriented
 - trouble talking or walking
 - muscles feel stiff or shaking
 - feel weak
 - feel grouchy or angry
 - feel nervous or anxious

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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

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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: 8am – 8pm ET

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Zip Code

Radius

- 1 mile
- 5 miles
- 10 miles
- 15 miles
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ZYPREXA RELPREVV Patient Care Program

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Scope

This Website Privacy Statement is provided by Lilly to all visitors ("you" or "your") who use the publicly available pages of the ZYPREXA RELPREVV Patient Care Program Website located at <https://www.zyprexarelprevvprogram.com/> (the "Site") and Authorized Users of the Patient Care Program Website. "Authorized Users" are eligible Prescribers, Healthcare Facilities and Pharmacy Service Providers. "Prescribers" include physicians, physician's assistants, nurse practitioners, and pharmacists. "Healthcare Facility" means a healthcare facility administering and/or monitoring injections of ZYPREXA RELPREVV. "Pharmacy Service Provider" means 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. The "Patient Care Program Website" is an Authorized User-only portal available through the Site which enables Authorized Users to prescribe ZYPREXA RELPREVV.

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You may visit most areas of this website without providing directly identifiable Personal Information or revealing your identity. However, in some cases you may choose to voluntarily provide Personal Information via this website in order to register for, or request, additional information or services, including obtaining access to the Patient care program website. In such cases, we will collect information that can identify you, such as your name, address, telephone, number, email address, and other similar information ("**Personal Information**").

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The type of access and services offered through the Patient Care Program Website may depend on whether you have registered as a Prescriber, a Healthcare Facility, or a Pharmacy Service Provider.

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ZYPREXA RELPREVV Patient Care Program

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