

**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](http://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.*

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**Marketed by: Lilly USA, LLC  
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**[www.zyprexarelprevv.com](http://www.zyprexarelprevv.com)**

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