NDA 22-173
Zyprexa® Relprevv™ (olanzapine)

For Extended Release Injectable Suspension
Eli Lilly and Company
Lilly Corporate Center, Indianapolis, Indiana 46285
Telephone: 317-276-2000

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-l(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-l(t)(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-l(t)(3)(C) who are specially certified under FDCA 505-l(t)(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:

   1. 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-l(t)(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-l(t)(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-l(t)(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 Se, 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;
      n. 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;

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

iii. Zyprexa Relprevv dose;

lv. 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

vu. 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.
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: ____________ ____________ ____________

month day year

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

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Reference ID: 4786995
To be enrolled in the ZYPREXA RELPREVV Patient Care Program, complete and fax this form to 1-877-772-9391.

**PATIENT INFORMATION**

First Name: ___________________________________________ MI: ______ Last Name: __________________________________________

Date of Birth: _______________________________________

Gender:  □ Male    □ Female

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

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

**PRESCRIBER INFORMATION**

First Name: ___________________________________________ MI: _____ Last Name: __________________________________________

License Number: ______________________________________ State of Issue: ______________________________________

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

Address Line 1: ______________________________________

Address Line 2: ______________________________________

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

□ Yes

□ No  (If No, complete next section)

**INJECTING/MONITORING FACILITY INFORMATION**

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

Address Line 1: ______________________________________

Address Line 2: ______________________________________

City: ______________________________________ State: _______ Zip: ______________________________________
PATIENT AGREEMENT

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

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

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

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

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

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

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

______________________________________________________________ Date: ___________ – ________ – ________
Signature

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.

______________________________________________________________ Date: ___________ – ________ – ________
Signature of Prescriber

Printed Name of Prescriber

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

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Reference ID: 4786995
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: __________________________

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.

Date: ____________ ____________ ____________

Pharmacist-in-Charge Signature

PHONE 1-877-772-9390   FAX 1-877-772-9391   www.zyprexarelprevvprogram.com
BUY & BILL* PHARMACY SERVICE PROVIDER REGISTRATION FORM

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

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

PHARMACY SERVICE PROVIDER INFORMATION

☐ Enrollment  ☐ Reenrollment

Facility Name: ________________________________________________________________

DEA Number:  ________________________________________________________________

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

Address Line 1: ________________________________________________________________

Address Line 2: ________________________________________________________________

City:  __________________________________ State:  ___________  Zip:  _______________________

Primary Phone:  ___________________________  Secondary Phone:  ___________________________

Fax:  ___________________________

SHIP TO INFORMATION

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

Ship To 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:  ___________________________

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:  ___________  ___________  ___________

* 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.
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)

Email: ________________________________________________________________

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)

Email: ________________________________________________________________

Delegate First Name: ___________________________ MI: _____ Last Name: ______________________

Facility Name: ________________________________________________________________

Phone: ___________________________ Fax: ___________________________ (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  www.zyprexarelprevprogram.com

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Reference ID: 4786995
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

Authorized Healthcare Facility Representative Name (print) _______________________________ Title  ______________________________

Date: 

month - day - year

Please fax completed form to the ZYPREXA RELPREVV Patient Care Program at 1-877-772-9391.
The goal of this presentation is to educate healthcare professionals in an effort to mitigate negative outcomes associated with ZYPREXA RELPREVV post-injection delirium/sedation syndrome (PDSS). Healthcare professionals include: physicians, nurses and any other professionals who will be involved with the care of the patient receiving the injection.

Please see the Prescribing Information and the Reconstitution and Administration Poster before using ZYPREXA RELPREVV.
ZYPREXA RELPREVV™, also known as (olanzapine) For Extended Release Injectable Suspension, is the long-acting injectable form of ZYPREXA (olanzapine).

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

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

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

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

Because the active ingredient of ZYPREXA RELPREVV is the same as oral ZYPREXA® (olanzapine), ZYPREXA RELPREVV also carries the same boxed warning as oral ZYPREXA regarding increased mortality in elderly patients with dementia-related psychosis. ZYPREXA RELPREVV is not approved for the treatment of patients with dementia-related psychosis.
At the end of this training, you should be able to:

- Differentiate between ZYPREXA RELPREVV (olanzapine for extended release injectable suspension) and ZYPREXA IntraMuscular (olanzapine for injection) to avoid medication errors,
- Understand the dosing options with ZYPREXA RELPREVV,
- Know the common adverse events associated with ZYPREXA RELPREVV and how to monitor patients for metabolic changes,
- Identify a post-injection delirium/sedation syndrome (PDSS) event in your clinical practice,
- Know the conditions of safe use and how to manage the risk of PDSS,
- Know what to do in case a PDSS event occurs,
- Understand basics of the ZYPREXA RELPREVV Patient Care Program.
**ZYPREXA RELPREVV and ZYPREXA IntraMuscular** – Although both have olanzapine as their active ingredient and both are injected intramuscularly, they are intended for different indications and different dosing schedules.

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

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

Version 2.0, 03-Aug-2012

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

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

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

- **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.

Reference ID: 4786995
Transition

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

Key points

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

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

None of these events were statistically significantly different.

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

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

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

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

<table>
<thead>
<tr>
<th>Increasing ZYPREXA RELPREVV Dose</th>
<th>150 mg/2 wk</th>
<th>405 mg/4 wk</th>
<th>300 mg/2 wk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.67</td>
<td>0.89</td>
<td>1.70&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
<tr>
<td>Prolactin (μg/L)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>-5.61</td>
<td>-2.76</td>
<td>3.57&lt;sup&gt;††&lt;/sup&gt;</td>
</tr>
<tr>
<td>Fasting triglycerides&lt;sup&gt;b&lt;/sup&gt;</td>
<td>6.5%</td>
<td>9.8%</td>
<td>24.5%&lt;sup&gt;††&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> Mean change
<br><sup>b</sup> Change from normal at baseline to high at any time (%)
<br>▲P<.05 versus 150 mg/2 wk
<br>▲P<.05 versus 405 mg/4 wk

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

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.
Metabolic Monitoring

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

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

- Because the active ingredient of ZYPREXA 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
Metabolic Monitoring

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

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

• Undesirable lipid alterations have been observed during treatment with olanzapine. Clinical monitoring, including baseline and follow-up lipid evaluations, is advised.

• Clinically significant and sometimes very high elevations in triglycerides have been observed during olanzapine use. Modest mean increases in total cholesterol have also been observed.

• Patients should be monitored regularly for weight gain during treatment with olanzapine. Prescribers should consider the potential consequences of weight gain prior to initiating treatment.
In premarketing clinical trials, an unexpected degree of delirium and/or sedation was reported in a small number of patients with schizophrenia shortly after receiving an injection. This event has been termed Post-injection Delirium/Sedation Syndrome, or PDSS.

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

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

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

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

*As of 16 June 2000. Data on file, Lilly Research Laboratories, ZYPREXARelprevv (olanzapine) for Extended Release Injectable Suspension

What is Post-injection Delirium/Sedation Syndrome?

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

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

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

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

It is important to note that all patients who experienced a post-injection syndrome event largely recovered within 72 hours. Time of full recovery has ranged from 1.5 to 72 hours, with full recovery defined as the absence of signs or symptoms of the event. Approximately 70% of these patients chose to continue receiving ZYPREXA RELPREVV following the event.
Because there is a risk of a PDSS event with each injection, the following precautions should be followed every time a patient receives a ZYPREXA RELPREVV injection. For a description of the product reconstitution and administration procedures, please review the Reconstitution and Administration Poster and training video available on the ZYPREXA RELPREVV Patient Care Program web site.

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

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

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

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

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

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

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

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

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

- There is no specific antidote for olanzapine overdose. Patients experiencing PDSS should be managed as clinically appropriate and may be treated symptomatically in a facility capable of resuscitation.

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

- If the patient is sent to a hospital for further observation and/or management, it is recommended that the prescribing healthcare professional notify the hospital personnel that the patient is experiencing a probable olanzapine overdose following injection of ZYPREXA RELPREVV.

- It is very important that you report any suspected PDSS event through the ZYPREXA RELPREVV Patient Care Program within 24 hours of becoming aware of the event.
Clinical Management Following PDSS Events

Following a PDSS event

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

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

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

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

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

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.

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

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

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

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

Prescriber obligations include:

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

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
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.
The healthcare facility where a patient will receive the injection of ZYPREXA RELPREVY must also enroll in the ZYPREXA RELPREVY 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 RELPREVY Patient Care Program Instructions Brochure as well as the Training Materials
- Ensuring that all appropriate staff understand that ZYPREXA RELPREVY can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services 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 RELPREVY is only administered to patients enrolled in the program, and that patients are continuously monitored for at least 3 hours post-injection for suspected PDSS
- Ensuring that appropriate staff will verify that the patient is enrolled in the ZYPREXA RELPREVY Patient Care Program registry prior to each injection by accessing the system
- 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 RELPREVY Patient Care Program
- Understanding the facility may be contacted by the ZYPREXA RELPREVY 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. Version 2.0 03 Aug 2012
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 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, 09 Aug 2012
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.

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.
Title: ZYPREXA RELPREVV Reconstitution and Administration Training Video

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

1. Introduction
2. Post-injection Delirium/Sedation Syndrome
3. Step 1: Prepare Materials
4. Step 2: Determine Volume
5. Step 3: Reconstitute
6. Step 4: Inject
7. Ventrogluteal Injection
8. Dorsogluteal Injection
9. Recap
10. Play All

**ZYPREXA RELPREVV**
Reconstitution and Administration Training Video

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## Introduction

**Text on-screen:**
ZYPREXA RELPREVV logo

ZYPREXA RELPREVV Reconstitution and Administration Training

**Text on-screen:**
ZYPREXA RELPREVV logo

Chapter One: Introduction

**Music**

**Text on-screen:**
ZYPREXA RELPREVV (olanzapine) For Extended Release Injectable Suspension is an antipsychotic agent indicated for the treatment of schizophrenia in adults.

**Music**

**Text on-screen:**
All healthcare professionals who administer this product must view this video before giving an injection of ZYPREXA RELPREVV.

For important safety information, including boxed warnings, see the full prescribing information provided.

**Visual:**
Nurse (talent) talking to camera

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 the treatment of schizophrenia in adults.

**Text on-screen:**
Vial Strengths:
- 210-mg, 300-mg, and 405-mg

Dosing Schedules:
- Every 2 weeks: 150-mg, 210-mg, or 300-mg
- Every 4 weeks: 300-mg or 405-mg

**Visual:**
Nurse talking to camera

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.

**Text on-screen:**
The purpose of this video is to teach you how to properly reconstitute and administer ZYPREXA RELPREVV.

**Text on-screen:**
- 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

**Visual:**
Nurse talking to camera

First we will begin by explaining the Post-Injection Delirium/Sedation Syndrome events that occurred with ZYPREXA RELPREVV in pre-marketing clinical trials.

Then, we will demonstrate step-by-step instructions on how to properly reconstitute the product.

Once it has been reconstituted, we will show you the proper administration techniques and demonstrate the entire reconstitution and administration process in real time.
### Visual:
Nurse talking to camera

Please watch the end of this video and see accompanying full prescribing information for important safety information including boxed warnings.

### Post-Injection Delirium/Sedation Syndrome

#### Text on screen:
- ZYPREXA RELPREVV logo
- Chapter Two: Post-Injection Delirium/Sedation Syndrome

#### Visual:
Nurse talking to camera

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

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

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

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

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

#### Text on screen:
- PDSS Symptom Onset:

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

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

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

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

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

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

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

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

Reference ID: 4786995
<table>
<thead>
<tr>
<th><strong>Text on Screen:</strong></th>
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</thead>
<tbody>
<tr>
<td>Notify hospital or ER personnel of:</td>
</tr>
<tr>
<td>• “…a probable olanzapine overdose following administration of Olanzapine For Extended Release Injectable Suspension.”</td>
</tr>
</tbody>
</table>

| **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.”** |

<table>
<thead>
<tr>
<th><strong>Text on Screen:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Important:</td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

| **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.** |

<table>
<thead>
<tr>
<th><strong>Text on Screen:</strong></th>
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</thead>
<tbody>
<tr>
<td>After each ZYPREXA RELPREVV injection:</td>
</tr>
<tr>
<td>• Patients should be observed for at least 3 hours by appropriately qualified personnel in a healthcare facility with ready access to emergency response services</td>
</tr>
<tr>
<td>• The patient should be located where he or she can be seen and/or heard at all times</td>
</tr>
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<tr>
<th><strong>Text on Screen:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Before the patient leaves the healthcare facility:</td>
</tr>
<tr>
<td>• Confirm that the patient is alert, oriented, and without signs or symptoms of a post-injection delirium/sedation syndrome event</td>
</tr>
<tr>
<td>• 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</td>
</tr>
<tr>
<td>• All patients should be accompanied to their next destination upon leaving the facility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Before the patient leaves the healthcare facility:</strong></th>
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<th><strong>Text on Screen:</strong></th>
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<tbody>
<tr>
<td>After patient leaves the healthcare facility:</td>
</tr>
<tr>
<td>• Patients should not drive or operate heavy machinery for the remainder of the day</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th><strong>Visual:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse talking to camera</td>
</tr>
</tbody>
</table>

| **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.** |

Reference ID: 4786995
| **Text on-Screen:** | Increased contact with blood can occur:  
• Partial injection into vasculature  
• Significant vessel injury during IM injection (nick or puncture)  
• Substantial bleeding at injection site | ZYPREXA RELPREVV is much more soluble in blood than in muscle. Increased contact with a substantial volume of blood could occur in several ways, such as:  
• Partial injection into vasculature  
• Vessel injury associated with the intramuscular injection (a nick or puncture of the blood vessel)  
• And substantial bleeding at injection site |
| **Text on-Screen:** | Deep intramuscular gluteal injection:  
• Intended for deep muscular gluteal injection only  
  ○ Not for intravenous, subcutaneous, or deltoid injection  
• Aspirate syringe prior to injection to ensure no blood is visible  
• If blood is visible, discard the syringe and use a new product kit | Therefore, ZYPREXA RELPREVV is intended for deep intramuscular gluteal injection only. It is important to aspirate the syringe prior to injection to ensure no blood is visible. Administrators must not proceed with the injection if blood is visible. If blood is visible, discard the syringe and use a new product kit. |
| **Visual:** | Nurse talking to camera | Post-injection Delirium/Sedation Syndrome can occur at any injection, so safety precautions should be observed every time the product is administered. |
| **Step 1 – Prepare Materials** | **Text on-screens:**  
ZYPREXA RELPREVV logo  
Chapter Three  
Step 1 – Prepare Materials | **Music** |
| **Visual:** | Nurse talking to camera | Let’s begin by preparing for the ZYPREXA RELPREVV injection. |
| **Visual:** | Nurse talking to camera | First, you will need to gather and prepare your materials. |
| **Visual:** | Nurse talking to camera | Obtain 1 pair of gloves, several alcohol wipes, and the prescribed dose of ZYPREXA RELPREVV. |
| **Visual:** | Nurse talking to camera | The medication comes packaged in a convenience kit that includes the following items: |
| **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. | 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. |
| **Visual:** | Nurse talking to camera | Open the kit, remove all items, and arrange them conveniently to prepare for reconstitution. |
| **Visual:** | Nurse talking to camera | You will need to wear gloves when reconstituting ZYPREXA RELPREVV, as the medication can be irritating to the skin. |
| **Visual:** | Nurse talking to camera | If the medication contacts skin, flush it with water. |

Reference ID: 4786995
<table>
<thead>
<tr>
<th>Step 2 – Determine Reconstitution Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Text on screen:</strong></td>
</tr>
<tr>
<td>ZYPREXA RELPREVV logo</td>
</tr>
<tr>
<td>Chapter Four</td>
</tr>
<tr>
<td>Step 2 – Determine Reconstitution Volume</td>
</tr>
<tr>
<td><strong>Music</strong></td>
</tr>
<tr>
<td><strong>Visual:</strong></td>
</tr>
<tr>
<td>Nurse talking to camera</td>
</tr>
<tr>
<td>Next you will need to determine the reconstitution volume.</td>
</tr>
<tr>
<td><strong>Visual:</strong></td>
</tr>
<tr>
<td>C/U of table on reconstitution and administration instructions</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>Visual:</strong></td>
</tr>
<tr>
<td>Nurse talking to camera</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>Text on-screen:</strong></td>
</tr>
<tr>
<td>There will be excess diluent remaining in the vial</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reconstitute</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Text on screen:</strong></td>
</tr>
<tr>
<td>ZYPREXA RELPREVV logo</td>
</tr>
<tr>
<td>Chapter Five</td>
</tr>
<tr>
<td>Reconstitute</td>
</tr>
<tr>
<td><strong>Music</strong></td>
</tr>
<tr>
<td><strong>Visual:</strong></td>
</tr>
<tr>
<td>Nurse talking to camera</td>
</tr>
<tr>
<td>Now you are ready to reconstitute ZYPREXA RELPREVV. The process of reconstitution and administration should take around 5 minutes to complete.</td>
</tr>
<tr>
<td><strong>Visual:</strong></td>
</tr>
<tr>
<td>Hands tapping powder vial and wiping vials with alcohol wipes</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>Visual:</strong></td>
</tr>
<tr>
<td>Hands withdrawing diluent into syringe</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>Visual:</strong></td>
</tr>
<tr>
<td>Hands injecting diluent into powder vial</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>Visual:</strong></td>
</tr>
<tr>
<td>Hands tapping the vial</td>
</tr>
<tr>
<td><strong>Text on screen:</strong></td>
</tr>
<tr>
<td>Tap firmly and repeatedly</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>Visual:</strong></td>
</tr>
<tr>
<td>Hands tap and shake vial</td>
</tr>
<tr>
<td>Check for clumps by inspecting the sides and bottom of the vial. Unsuspended powder appears as light yellow, dry clumps clinging to the vial.</td>
</tr>
</tbody>
</table>
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.

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.

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.

For all doses, the concentration of olanzapine in the suspension is 150 mg per 1 ml.

When preparing to draw up the prescribed dose, refer to the table in the instructions for the correct injection volume.

For a prescribed dose of 210 mg, you will withdraw 1.4 ml from the reconstituted vial.

To prevent the product from leaking from the stopper, do not add air to the vial. Slowly withdraw the desired amount into the syringe. By doing this slowly, you will avoid excess air bubbles being drawn into the syringe.

There will be excess medication remaining in the vial.

To ensure the full dose is given, tap the syringe with your fingers to remove all excess air bubbles.

Once the desired dose is withdrawn, remove the needle from the vial, and engage the needle safety device.

Attach a new safety needle to the syringe.

Attach a new safety needle to the syringe.

Reference ID: 4786995
### Important:
Prior to administration, you must make sure that the patient receiving ZYPREXA RELPREVV will be accompanied to his or her destination following the 3-hour observation period.

If this cannot be confirmed, do not give the injection.

### Important:
Even if accompanied, the patient may not drive to his or her destination for the rest of the day.

### Text on screen:
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.

### Visual:
C/U of syringe

Now you are ready to give the injection of ZYPREXA RELPREVV. Once the medication is drawn into the syringe, it should be injected immediately.

### Visual:
Nurse talking to camera

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.

### Visual:
C/U of anatomical model and hands giving injection

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.

### Ventrogluteal Injection

### Text on screen:
ZYPREXA RELPREVV logo

Chapter Seven
Ventrogluteal Injection

### Visual:
C/U of practice ventrogluteal injection process on anatomical model

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.

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.

Insert the needle into the muscle, then aspirate slowly for several seconds by pulling back on the plunger of the syringe.

### Visual:
Nurse talking to camera

If any blood is drawn into the syringe, discard the syringe and the dose, and begin with a new kit.

### Visual:
C/U on hands giving injection

In this case, no blood is seen, so we will inject the medication with steady pressure.
<table>
<thead>
<tr>
<th>Visual:</th>
<th>Text on-screen:</th>
</tr>
</thead>
<tbody>
<tr>
<td>C/U of hands withdrawing needle and engaging safety device</td>
<td>After withdrawing the needle carefully from the muscle, engage the needle safety device.</td>
</tr>
<tr>
<td>Nurse talking to camera</td>
<td>Do not massage the injection site</td>
</tr>
<tr>
<td>C/U of hands disposing vial, needle, and syringe</td>
<td>Finally, after the injection, make sure to dispose of the vials, needles, and syringe appropriately.</td>
</tr>
</tbody>
</table>

**Dorsogluteal Injection**

<table>
<thead>
<tr>
<th>Text on-screen:</th>
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<tbody>
<tr>
<td>ZYPREXA RELPREVV logo</td>
</tr>
</tbody>
</table>

**Chapter Eight**

**Dorsogluteal Injection**

<table>
<thead>
<tr>
<th>Visual:</th>
</tr>
</thead>
<tbody>
<tr>
<td>C/U of practice dorsogluteal injection process on anatomical model</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Visual:</th>
<th>Text on-screen:</th>
</tr>
</thead>
<tbody>
<tr>
<td>C/U of hands withdrawing needle and engaging safety device</td>
<td>After withdrawing the needle carefully from the gluteal muscle, engage the needle safety device.</td>
</tr>
<tr>
<td>Nurse talking to camera</td>
<td>Do not massage the injection site.</td>
</tr>
<tr>
<td>C/U of hands disposing vial, needle, and syringe</td>
<td>Finally, after the injection, make sure to dispose of the vials, needles, and syringe appropriately.</td>
</tr>
</tbody>
</table>

**Recap**

<table>
<thead>
<tr>
<th>Text on-screen:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZYPREXA RELPREVV logo</td>
</tr>
</tbody>
</table>

**Chapter Nine**

**Recap**

Music

To summarize, the process of reconstituting and administering ZYPREXA RELPREVV can be broken down into four easy steps.
<table>
<thead>
<tr>
<th>Text on-screen:</th>
<th>One, prepare materials; two, determine reconstitution volume; three, reconstitute; and four, inject.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prepare Materials</td>
<td></td>
</tr>
<tr>
<td>• Determine Reconstitution Volume</td>
<td></td>
</tr>
<tr>
<td>• Reconstitute</td>
<td></td>
</tr>
<tr>
<td>• Inject</td>
<td></td>
</tr>
<tr>
<td>Visual:</td>
<td>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.</td>
</tr>
<tr>
<td>Nurse talking to camera</td>
<td></td>
</tr>
<tr>
<td>Visual:</td>
<td>Music</td>
</tr>
<tr>
<td>Real-time reconstitution process with timer</td>
<td></td>
</tr>
<tr>
<td>Text on Screen:</td>
<td>If you have any questions about reconstituting and administering ZYPREXA RELPREVV please contact the number on-screen or visit the following website.</td>
</tr>
<tr>
<td>1-800-LillyRx</td>
<td></td>
</tr>
<tr>
<td>(1-800-545-5979)</td>
<td></td>
</tr>
<tr>
<td><a href="http://www.ZyprexaRelprevv.com">www.ZyprexaRelprevv.com</a></td>
<td></td>
</tr>
</tbody>
</table>
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.
Enrolled Pharmacy Service Provider places ZYPREXA RELPREVV order with regular wholesaler

Order is forwarded to Lilly/Specialty Distributor

Lilly/Specialty Distributor verifies Pharmacy Service Provider eligibility via the on-line system

ZYPREXA RELPREVV Patient Care Program Database and Coordinating Center

Pharmacy Service Provider receives ZYPREXA RELPREVV

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

Pharmacy Service Provider confirms patient eligibility via the on-line system or via the Interactive Voice Response System (IVRS)

Patient eligibility is confirmed

Pharmacy Service Provider dispenses ZYPREXA RELPREVV to registered healthcare facility as indicated by the on-line system or IVRS and enters dispense date via the on-line system or IVRS.

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

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

Healthcare Facility Activities
- 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

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

Patient Activities
- 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

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

*For the first prescription include the patient authorization notification

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

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

*PDSS = post-injection delirium/sedation syndrome

Reference ID: 4786995
For questions regarding the Patient Care Program or to enroll, please contact the Patient Care Program Coordinating Center:

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

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

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

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

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

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.

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.**
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
     - 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.
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.

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.zyprexarelprevvprogram.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.

### 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.
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](http://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.
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)  
Patient Name: _________________________________________

Date of Birth: ___/___/___

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: ___/___/___

Time of ZYPREXA RELPREVV injection: ___:___

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

Healthcare Facility Staff Member Name (print): _________________________________

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

CONFIDENTIAL

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Reference ID: 4786995
**INJECTION Multiple Patients**

**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**

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**Patient No.: (PIN)**

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**Patient Name:**

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<th>First Name</th>
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**Date of Birth:**

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<thead>
<tr>
<th>month</th>
<th>day</th>
<th>year</th>
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**PDSS since last visit? (check one)**

- Yes
- No

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

- Yes
- No

**Time of Injection**

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**Dose of Injection**

- 150 mg
- 210 mg
- 300 mg
- 405 mg
- Other dose _________ mg

**Observed at least 3 hours post-injection? (check one)**

- Yes
- No

**PDSS during onsite observation? (check one)**

- Yes
- No

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

- Yes
- No

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

- Yes
- No

**Following the injection, was the patient accompanied from the facility? (check one)**

- Yes
- No

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

**Signature**

**Healthcare Facility Staff Member Name (print):**

<p>| | | |</p>
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**Was the patient or legal guardian given a Medication Guide prior to this injection?**

- Yes
- No

**Phone 1-877-772-9390**

**FAX 1-877-772-9391**

**www.zyprexarelprevvprogram.com**

**Version 2.0**

**August 2012**

**CONFIDENTIAL**

**Reference ID: 4786995**
Does the patient have a diagnosis of schizophrenia?  

Yes  

No

**PATIENT/INJECTION INFORMATION**

Date of Injection:  

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:  

Weight:

**PDSS SIGNS AND SYMPTOMS**

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

☐ Aggressiveness  

☐ Coma  

☐ Hypertension  

☐ Tachycardia  

☐ Agitation  

☐ Confusion  

☐ Hypotension  

☐ Various extrapyramidal symptoms  

☐ Anxiety  

☐ Convulsion/Seizure  

☐ Other cognitive impairment  

☐ Weakness  

☐ Aspiration  

☐ Delirium  

☐ Possible neuroleptic malignant syndrome  

☐ Other ________________  

☐ Ataxia  

☐ Disorientation  

☐ Reduced level of consciousness  

☐ Other ________________  

☐ Cardiac arrhythmias  

☐ Dizziness  

☐ Respiratory depression  

☐ Other ________________  

☐ Cardiopulmonary arrest  

☐ Dysarthria  

☐ Sedation  

☐ Other ________________
PDSS start date: 

PDSS resolution date: 

If resolved, duration of PDSS: ____________________________  

Minutes  Hours  Days  OR  Ongoing

Are these PDSS symptoms related to ZYPREXA RELPREVV?  

Yes  No - Please Explain _________________________________________________________________________________________

Describe the clinical course _______________________________________________________________________________________
_____________________________________________________________________________________________________________

Patient Outcome:  (choose one)  

Recovered  Fatal  Not Recovered  Recovering  Recovered with sequelae

Once a PDSS event was suspected, was the patient’s monitoring initiated in a facility capable of resuscitation?  

Yes  No

Did the patient visit the emergency room as a result of the PDSS?  

Yes  No

Was the patient admitted to the hospital as a result of the PDSS?  

Yes  No

Were olanzapine concentrations collected?  

Yes  No

Did the patient receive any MEDICATIONS AS TREATMENT for the PDSS event?  

Yes - Please record below  No

<table>
<thead>
<tr>
<th>Treatment Medication Name</th>
<th>Dose</th>
<th>Duration of Use (in Days)</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>
POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.: _______ _______ _______ _______ _______ _______
(PIN)

Patient Name: _________________________________________      _________       _________________________________________
First Name                                                                            MI                      Last Name

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

☐ Assisted ventilation  ☐ EEG  ☐ MRI  ☐ Urine drug screen
☐ Brain CT  ☐ IV fluids  ☐ Observation/symptomatic management  ☐ Vital sign monitoring
☐ ECG  ☐ Labs  ☐ Restraints  ☐ Other ______________

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

HISTORY PRIOR TO PDSS EVENT

Does the patient have any relevant comorbidities?
☐ Yes - Please specify: __________________________________________________________________________________________________
☐ No

PRIOR MEDICATIONS

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

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

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

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

Event reported by: _________________________________________      _________       _________________________________________
First                                                                                 MI                    Last

Title/Occupation: ___________________________________________________________________________________________________

If agent of the Prescriber, name of Prescriber: _________________________________________      _________      ______________________________

Reference ID: 4786995
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
Select your role(s) from the list below to access required training.

Prescriber
Healthcare Facility Staff
Pharmacy Service Providers (pharmacies and buy & bill pharmacy service providers)
Required Prescriber Training

1. ZYPREXA RELPREVY Patient Care Program Instructions Brochure
2. Healthcare Professional Training (select one)
   • Slide Presentation
   • Recorded Presentation

ADDITIONAL RESOURCES

Post-Injection Delirium/Sedation Syndrome Case Study Video

Once you have completed the required training, submit the appropriate registration form.
Required Prescriber Training

1. ZYPREXA RELPREVV
2. Healthcare Professionals
   • Slide Presentation
   OR
   • Recorded Presentation

ADDITIONAL RESOURCES

Post-Injection Delirium/Sedation Syndrome

Once you have completed the required training, you will receive a certificate of completion.

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VERSION: 1.35.8.1 PP-00-03-0004 11/23/21
Site hosted by UBC
Required Prescriber Training

1. ZYPREXA RELPREVV Patient Care Program Instructions Brochure
2. Healthcare Professional Training (select one)
   - Slide Presentation

https://www.zyprexarelprevvprogram.com/public/home.htm
1. ZYPREXA RELPREVV Patient Care Program Instructions Brochure
2. Healthcare Professional Training (select one)
   • Slide Presentation
1. **ZYPREXA RELPREVV Patient Care Program Instructions Brochure**
2. Healthcare Professional Training (select one)
Required Healthcare Facility Staff Training

1. Healthcare Professional Training (select one)
   - Slide Presentation
   OR
   - Recorded Presentation

2. ZYPREXA RELPREV Vancouver Patient Care Program Instructions Brochure

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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Version: 134119-00-0010-004 10/2021
Site hosted by USBC
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 (PIDS). Healthcare professionals include physicians, nurses, and any other professionals who will be involved with the care of the patient receiving the injection.
ZYPREXA RELPREVV Patient Care Program

Required Healthcare Facility Staff Training

ZYPREXA RELPREVV Patient Care Program Instructions Brochure

Zyprexa Relprevv™
(olanzapine) For Extended Release Injectable Suspension
Instructions to Reconstitute and Administer ZYPREXA RELPREVV

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

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
ZYPREXA RELPREVV Patient Care Program

Required Healthcare Facility Staff Training

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

ZYPREXA Relprevv
(olanzapine) For Extended Release Injectable Suspension
215 mg/vial, 300 mg/vial, and 405 mg/vial
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.
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
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**
To be enrolled in the ZYPREXA RELPREV Patient Care Program, complete this form.
Training must be completed before a prescriber may be enrolled in the ZYPREXA RELPREV Patient Care Program.

**PRESCRIBER INFORMATION**

- **First Name:** 
- **Last Name:** 
- **Degree:** □ MD □ DO □ NP □ PA □ Nurse with prescriptive authority □ Other with prescriptive authority
- **License Number:** 
- **State of Issue:**
- **Treatment Facility/Practice (where you see your patients):**

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

- **Address Line 1:** 
- **Address Line 2:**
- **City:** 
- **State:** 
- **Zip:**
- **Phone:** [ ] [ ] Alternate Phone: [ ] [ ]
- **Fax:** [ ] [ ] Prescriber Email:

**Preferred Method of Communication:** □ Email □ Fax

**PRESCRIBER AGREEMENT**

By signing below, I acknowledge that:

- □ I understand the ZYPREXA RELPREV Patient Care Program requirements and the risks associated with ZYPREXA RELPREV.
- □ I have completed the mandatory ZYPREXA RELPREV training.
- □ I understand the clinical presentation of post-injection delirium/sedation syndrome (PODS) and how to manage patients should an event occur while using ZYPREXA RELPREV;
- □ I understand that ZYPREXA RELPREV should only be initiated in patients for whom tolerability with oral olanzapine has been established;
- □ I understand that ZYPREXA RELPREV 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 report all suspected cases of PODS are reported to the ZYPREXA RELPREV Patient Care Program within 24 hours of becoming aware of the event.
ZYPREXA RELPREVV Patient Care Program

Prescriber Registration Form

City: [ ] Stater: [ ] 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 support 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’s 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 1-877-772-9391.

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 1-877-772-9391 Fax 1-877-772-9391 www.zypréxarelprevpro

registration/SubmitForm.aspx?ID=4
PRINCIPAL REGISTRATION FORM

City: __________________________ State: __________ Zip: ________

Phone: ______ Alternate Phone: ______

Fax: ______ Prescriber Email: ______

Preferred Method of Communication: □ Email □ Fax

PRINCIPAL 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.

☐ 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 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.

☐ I will review the ZYPREXA RELPREVV Medication Guide with each patient.

☐ I understand that the ZYPREXA RELPREVV Patient Care Program will be monitored for efficacy and tolerability.

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 1-877-772-9391.

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.zyprexaelprevprogram.com

Registration?Register.aspx?ID=3
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

Please see Prescribing Information for full details about the risks of ZYPREXALORPREV. Including Buried Warnings.
This site is intended for U.S. residents age 18 and over.
For more information about ZYPREXALORPREV, contact your doctor or other healthcare professionals.
**PHARMACY REGISTRATION FORM**

**PHARMACY INFORMATION**
- 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: 

**SHIPPING 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: 

**PHARMACIST-IN-CHARGE AGREEMENT**
- By signing below, I acknowledge that: 
  - registration@Relprev.com
REFERENCE ID: 4786995

ZYPREXA RELPREVV Patient Care Program

PHARMACY REGISTRATION FORM
City:  
State:  
Zip:  
Primary Phone: ( )  
Secondary Phone: ( )  
Fax: ( )  

PHARMACIST-IN-CHARGE INFORMATION
First Name:  
MI:  
Last Name:  
Email:  
Phone: ( )  
Fax: ( )  

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 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 ZYPREXA RELPREVV Informed Consent and Registration Program.
☐ 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 conveyance of the product to 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 pharmacy.

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 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 #:  

Phone 1-877-772-9391  FAX 1-877-772-9391  www.zyprexarelprevvprogram
PHARMACY REGISTRATION FORM

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 the necessary response services and that can allow for continuous patient monitoring for all patients receiving ZYPREXA RELPREVV.
☐ I will ensure that pharmacy staff will verify that the patient is enrolled in the program prior to dispensing each prescription/refill by accessing the ZYPREXA RELPREVV website (www.zyprexa-relpresv.com).
☐ I will ensure that pharmacy staff report the date of each ZYPREXA RELPREVV dispensing/prescription.
☐ I will ensure pharmacy staff report the date of each ZYPREXA RELPREVV dispensing/prescription to 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, I will notify the ZYPREXA RELPREVV Patient Care Program Coordinating Center by fax at 1-877-772-9391 or by phone at 1-877-772-9390.

☐ 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.
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

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVIV, including Boxed Warnings.
This site is intended for U.S. residents age 18 and over.
For more information about ZYPREXA RELPREVIV, contact your doctor or other healthcare professional.
<table>
<thead>
<tr>
<th><strong>PHARMACY SERVICE PROVIDER INFORMATION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility Name: ________________________</td>
</tr>
<tr>
<td>DEA Number: _________________________</td>
</tr>
<tr>
<td>Please specify description of Pharmacy:</td>
</tr>
<tr>
<td>☐ Community / Retail  ☐ Specialty Pharmacy</td>
</tr>
<tr>
<td>☐ Hospital or Institution  ☐ Other</td>
</tr>
<tr>
<td>Address Line 1: ______________________</td>
</tr>
<tr>
<td>Address Line 2: ______________________</td>
</tr>
<tr>
<td>City: ___________________________  State: _______  Zip: _______</td>
</tr>
</tbody>
</table>
| Primary Phone: (____) -_____  Secondary Phone: (____) -_____
| Fax: ___________________________ |

<table>
<thead>
<tr>
<th><strong>SHIP TO INFORMATION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ship To Address (if the same as above check here) ☐</td>
</tr>
<tr>
<td>Ship To Contact Name: ______________________</td>
</tr>
<tr>
<td>Address Line 1: ______________________</td>
</tr>
<tr>
<td>Address Line 2: ______________________</td>
</tr>
<tr>
<td>City: ___________________________  State: _______  Zip: _______</td>
</tr>
</tbody>
</table>
| Primary Phone: (____) -_____  Secondary Phone: (____) -_____
| Fax: ___________________________ |

<table>
<thead>
<tr>
<th><strong>ADMINISTRATOR INFORMATION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name: __________________</td>
</tr>
<tr>
<td>MI: ___  Last Name: __________</td>
</tr>
<tr>
<td>Preferred Method of Communication: ☐ Email  ☐ Fax</td>
</tr>
<tr>
<td>Email: ________________________</td>
</tr>
<tr>
<td>Phone: (<strong><strong>) -_____  Fax: (</strong></strong>) -_____</td>
</tr>
</tbody>
</table>

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.
BUY AND BILL PHARMACY SERVICE PROVIDER REGISTRATION FORM

City: ___________________________ State: ______ Zip: ______

Primary Phone: (____)______ Secondary Phone: (____)______
Fax: (____)______

ADMINISTRATOR INFORMATION

First Name: ___________________ M.I.: _____ Last Name: ___________________

Preferred Method of Communication: □ Email □ Fax

Email: _________________________ Fax: (____)______
(If different from above) (If different from above)

PHARMACY SERVICE PROVIDER AGREEMENT

By signing below, I acknowledge that:

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

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

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

Confirm DEA #: ________________________

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

Phone 1-877-772-9391   FAX 1-877-772-9391   www.zyprexa-patient-care-program.com
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
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
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

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

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

**HEALTHCARE FACILITY INFORMATION**

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.

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

<table>
<thead>
<tr>
<th>Healthcare Facility Name:</th>
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Please specify location of Healthcare Facilities:

- Prescriber Office
- Clinic / Outpatient Facility
- Hospital
- Other

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<th>Address:</th>
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<th>Phone:</th>
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**AUTHORIZED HEALTHCARE FACILITY REPRESENTATIVE INFORMATION**

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<tr>
<th>First Name:</th>
<th>M1:</th>
<th>Last Name:</th>
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<th>Position/Title:</th>
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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:**

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<th>Facility Name:</th>
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**Delegate First Name:**

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<th>Facility Name:</th>
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HEALTHCARE FACILITY AGREEMENT

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

☐ I have read and understand the ZYPREXA RELPREVX Patient Care Program Instructions Brochure;

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

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

☐ I will ensure the healthcare setting has systems, protocols, or other measures to ensure that ZYPREXA RELPREVX is only administered to patients enrolled in the program and that the patient is monitored for at least 3 hours post-injection for suspected PSSS;

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

☐ I will ensure that the Medication Guide is provided to the patient prior to each injection;

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

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

☐ I understand that the ZYPREXA RELPREVX Patient Care Program Coordinating Center may contact the healthcare setting to clarify information provided or to obtain information about the patient.

I confirm that the information above is correct.

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

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

I understand that Lilly will regularly evaluate ZYPREXA RELPREVX Patient Care Program compliance to ensure that program objectives are met. Lilly reserves the right to terminate a healthcare setting's participation in the ZYPREXA RELPREVX Patient Care Program.
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:
  - 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 services and that can allow for continuous patient monitoring for at least 3 hours post-injection;

☐ I will ensure that 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 the patient is 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 above if necessary.

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 registration 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 revise or cancel 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.
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:
- 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 services and that can allow for continuous patient monitoring for at least 3 hours post-injection;
☐ I will ensure that 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, 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.
☐ I understand that the ZYPREXA RELPREVV Patient Care Program Coordinator will keep an updated list of information provided or to obtain information about the facility.

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 registration 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 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
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 RELPREVX Patient Care Program Instructions Brochure
  - Reconstitution & Administration Poster & Training Video (DVD)
  - Healthcare Professional Training Recorded Presentation (DVD) with Participant Guide
  - POSS Case Study Video (DVD)
  - Medication Guide
  - Prescribing Information

*Note: Patient Materials will automatically ship to a prescriber after prescriber registration is complete.
Training Material for Pharmacy Service Providers
(Traditional pharmacy operation or buy & bill prescriber)

- ZYPREXA RELPREVV Patient Care Program Instructions Brochure

Training Materials Available as Individual Items

- ZYPREXA RELPREVV Patient Care Program Instructions Brochure
- Reconstitution & Administration Poster
- Reconstitution & Administration Training Video (DVD)
- Healthcare Professional Training Recorded Presentation (DVD) with participant guide
- PDSS Case Study Video (DVD)

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

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
ZYPREXA RELPREVV Patient Care Program

Prescribing Information

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 DELIRIUMSEDIATION 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, 6.1, 6.2, 12.2, 17)
• 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, 8.5, 17)

RECENT MAJOR CHANGES
Warnings and Precautions, Tardive Dyskinesia (5.6) 10/2019
Warnings and Precautions, Use in Patients with Concomitant Illness (5.16) Removed 4/2020
Warnings and Precautions, Anticholinergic

• Elderly Patients with Dementia-Related Psychosis: Increased risk of death and increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack). (5.3)
• 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)
• Drop Reaction with Hypotension and Dystonic 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 severe 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 diziness, 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 response. (5.9)
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).
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 – 6pm ET

Please see Prescribing Information for full details about the role of ZYPREXA RELPREVV, including boxed Warnings.
This site is intended for U.S. residents age 18 and over.
For more information about ZYPREXA RELPREVV, contact your doctor or other healthcare professional.

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VERSION: 1.368.1 PR-OD-US-0864-032011
Site hosted by UBC
Eli Lilly and Company, its agents, affiliates, and authorized representatives (collectively, "Lilly", "we", "us" or "our") respects the privacy of visitors to our websites, and as a result, we have developed this Website Privacy Statement ("Privacy Statement"). United BioSource Corporation ("UBC") has been contracted by Lilly to host and manage the Site (as defined below) and to collect and analyze data on behalf of Lilly for the ZYPREXA RELPREV patient care program.

Scope

This Privacy Statement applies to Personal Information obtained by Lilly from all visitors ["you" or "your"] through the publicly available pages of the ZYPREXA RELPREV Patient Care Program Website located at https://www.zyprexaehrprevprogram.com/ (the "Site"), or otherwise, including, but not limited to, the delivery of our products and services (collectively, the "Services"), and Authorized Uses of the Patient Care Program Website. "Authorized Users" are eligible Prescribers, Healthcare Facilities and Pharmacy Service Providers. "Prescribers" include physicians, physician assistants, nurse practitioners, and pharmacists. "Healthcare Facility" means a healthcare facility administering and/or monitoring injections of ZYPREXA RELPREV. "Pharmacy Service Provider" means any retail pharmacy, hospital pharmacy, physician, or properly licensed healthcare facility that can order and deliver ZYPREXA RELPREV to a healthcare professional in accordance with their agreement to implement all relevant requirements of the ZYPREXA RELPREV 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 RELPREV. Please read this Privacy Statement carefully before you access the Site, use the Services, or otherwise provide Personal Information to us, whether online or offline.

The term "Personal Information" means any information that identifies, relates to, describes, is reasonably capable of being associated with, or could reasonably be linked, directly or indirectly, with a particular individual or household, including any information that is subject to applicable data protection laws. Personal Information may include any information, in any form, related to the past, present, or future health or medical status, condition, or treatment of a person, including, by way of example, but not limitation, names of doctors, health conditions, medicines, and/or prescription information and history. Personal Information may include "protected health information" ("PHI") as defined under the Health Insurance Portability and Accountability Act of 1996, as amended and implemented ("HIPAA), and "Personal Information" as defined under the California Consumer Privacy Act; Cal. Civ. Code §§ 1798.100 et. seq., as amended ("CCPA").

CONSENT TO PROCESSING IN THE UNITED STATES AND ELSEWHERE. This Site is owned and operated by Lilly in the United States, and the use and content of the Site and the Services is intended for U.S. residents only. Please note, however, the information you provide may be accessible to our affiliates, vendors and suppliers in other countries. If you are visiting this Site from a country other than the United States, information collected from you or this Site will be transferred outside of your country. The level of legal protection for Personal Information is not the same in all countries; however, we will take reasonable efforts and security measures as described in this Privacy Statement in an effort to keep your information secure.

These affiliates and/or third parties may be located in countries that do not ensure the same level of data protection but are required to treat Personal Information in a manner consistent with this Privacy Statement. To obtain additional information regarding the basis for transfers that Lilly has in place for cross-border transfers of Personal Information, which may include standard contractual clauses, existing adequacy decisions, or another cross-border data transfer mechanism deemed compliant under applicable data protection laws, please contact us at privacy@illy.com or visit https://www.illy.com/privacy.

By using this Site, you consent to the collection, storage and processing of your Personal Information in the United States and in any country to which we may transfer your information if the course of our business operations.

Personal Information We Collect

Information Routinely Collected by Our Website Technology

When you visit the Site, and during your interactions with the Site, web servers may automatically collect certain Internet Data from you. "Internet Data" means a data element or collection of data elements associated with your IP address, the Internet browser or computer operating system you are using, your navigation of the Site including the pages of the Site that you access, the amount of time spent on various portions of the Site, the length and dates of your visits to the Site, and certain Site data captured through your interactions with the Site and other sites. Certain Internet Data may be collected on an aggregated, anonymous basis through web server logs, cookies, ad servers, tracking pixels, web beacons, and similar Internet tracking devices (collectively, "Tracking Mechanisms"). However, based on certain interactions with the Site, third-party sites, mailings, other communications with us, and/or our system configurations, certain Internet Data can be identifiable with you.
Information You Voluntarily Provide

In some cases, you may choose to voluntarily provide certain Personal Information to this Site 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.

Registration. Registration is optional; however, you must register to become an Authorized User and only Authorized Users are provided access to the Patient Care Program Website and/or information and online services not provided on the public portions of the Site, as well as the ability to login to the Patient Care Program Website when revoking the Site. The Personal Information you disclose to us during registration and in connection with the Patient Care Program Website is provided strictly on a voluntary basis. You may register on the Patient Care Program Website by filling out a form and submit it to us online or otherwise. You will need to provide certain Personal Information including first name, last name, and/or email address to register. The type of access and services offered through the Patient Care Program Website may depend on whether you have registered as a Prescriber, a Healthcare Facility, or a Pharmacy Service Provider.

Health Information. When you become an Authorized User, you may be asked to provide us with certain Health Information of one or more patients with their consent, on whose behalf you are assisting in their care by a Healthcare Facility or a Pharmacy Service Provider, or patients that you are treating. After you login to the Patient Care Program Website, you may be able to view certain Health Information of your patients and use other services the Patient Care Program Website may offer. The term "Health Information" means any information, in any form, related to the past, present, or future health or medical status, condition, or treatment of a person, including, by way of example, but not limitation, names of doctors, health conditions, medicines, and/or prescription information and history. If you submit any Personal Information relating to other people to us, you represent that you have the authority to do so and to permit us to use the information in accordance with this Privacy Statement.

How We Use Your Personal Information

We may use your Personal Information to contact you and/or provide you with general Health Information (like information on certain health conditions) as well as information on our Services. We may enhance or merge your Personal Information with other data we may have about you as well as with data obtained from third parties for the same purposes.

We may use your Personal Information in one or more of the following ways:

- For Patient Care Program enrollment and certification.
- For dispensing and monitoring Zygeex Reliprev to patients.
- For testing, research, analysis, and product and service development, including to analyze and learn how the Site and the Services are used (e.g., via Tracking Mechanisms) to develop and improve them.
- To manage our vendor and partner relationships.
- To ensure the security and integrity of the Site.
- To assess and enforce compliance.
- To protect our and others' interests, rights, and property (such as to protect our copyrighted materials).
- To comply with applicable legal requirements, such as tax and other government regulations and industry standards, contracts, and law enforcement requests.

Information routinely collected may also be stored in databases owned and maintained by Lilly or its agents, contractors, and business partners. Lilly retains their respective rights to these databases and the information contained in them.

Cookies and Other Tracking Mechanisms. We may use Tracking Mechanisms to generate web log information, IP addresses, and other Internet Data routinely collected by our webservers in connection with your visit to this Site, to better understand your needs and general user traffic patterns, and to improve our Sites and Services. We may enhance or merge this Internet Data with other data we may have about you as well as with data obtained from third parties for the same purposes. We also may use your IP address to personalize content provided on the Site. We may retain IP addresses, and we may retain them together with other Personal Information. Our webservers can detect whether you have cookies on your computer. It is possible that a cookie may contain information that could be deemed identifiable. We may use the Internet Data we obtain through the use of cookies to customize your site experience by anticipating the information and services that may be of interest to you. We also analyze such Internet Data collected with cookie technology to help us improve the functioning of our Site by monitoring traffic in popular areas and to modify the Services and information we provide to meet customer demand. We may link the clickstream data available to us through the use of cookies to Personal Information that you may choose to provide elsewhere on our websites. We use the information we collect through the use of cookies for our business purposes, including operation of our Site, as well as research and product analyses to help us better market our Services. You can change your settings for cookies and similar technologies by clicking on the cookie consent box on the Site. In addition, you can refuse or accept cookies from the Site at any time by activating the settings on your browser. Most web browsers automatically accept cookies but allow you to modify your browser setting to block them. If you reject cookies, however, functionality of the Site may be limited, and you may not be able to take advantage of many of the Site's features. There are different methods for viewing and deleting cookies set on your machine, depending on the browser you are using. We recommend you visit the website of your web browser, where you should be able to find this information, or you can visit a site such as http://www.aboutcookies.org/default.aspx. Some mobile devices store cookies only in areas connected to the web browsers also in an app-specific area, so you may have to check your app settings options to determine how to manage or delete cookies stored in these other areas.

Third-Party Cookies and Advertising. We may partner with third party ad networks to manage our advertising on other sites. Our ad network partners use cookies and other Tracking Mechanisms to collect Internet Data about your activities on this and other websites to provide you targeted advertising based upon your interests. If you would like to opt-out of, or manage, cookies used for targeted advertising, you may do so by following the options provided by the Network Advertising Initiative at: http://www.networkadvertising.org/choices and the Digital Advertising Alliance at: http://www.aboutads.info/choices. Please note that opting out of receiving targeted ads will not prevent you from being served advertisements generally.

Digital Analytics. We may analyze Internet Data in the aggregate to study outcomes, costs, and provider profiles. These studies may generate Aggregate Data (described below) which may utilize for a variety of purposes, including product and service development and improvement activities and clinical research purposes.
We may perform statistical analyses of the traffic patterns, Site usage, and behaviors associated with the Site. We may use these analyses to generate Aggregate Data from the original Internet Data. We may combine, separate, aggregate, or otherwise process such information. The processing and processing of such information may generate Aggregate Data. "Aggregate Data" is a summary level data, such as the number of web visitors in a specific geographic area. Aggregate Data does not contain information that can be used to identify or contact you, such as your name, address, telephone number or e-mail address, and does not reflect the original form of the Internet Data collected from you.

Analytics UBC may use certain in-house or third-party functionality to analyze your communications with us and interactions with the Site. The analysis enables us to monitor the services that we provide so that we can improve our services provided to you. These third parties will be required to protect any Personal Information in a manner consistent with this Privacy Statement. Other analytics capabilities are reflected in the description of Internet Data.

Sharing Your Personal Information
We may share the Personal Information we collect through this Site and Services with our employees, agents, contractors or partners in connection with services that these individuals or entities perform for or with us. These agents, contractors or partners are restricted from using this data in any way other than to perform these services. Lilly expects our employees and partners to maintain the trust placed in us by those who provide us with information by using reasonable and appropriate administrative, technical and physical safeguards. Lilly and UBC reserve the right to share Personal Information to respond to duly authorized information requests of governmental authorities or where required by law. Lilly and UBC may share certain Personal Information collected by UBC on the Site with companies that sponsor and/or support the REMS Program and with the U.S. Food and Drug Administration. Please note, for purposes of the HIPAA Privacy Rule, the information you provide on the Site in furtherance of the REMS Program is not subject to HIPAA under the public health exception for government-mandated public health activities and purposes. In some circumstances, such as where national, state or company security is an issue, Lilly and UBC reserve the right to share our entire database of visitors and customers, and the associated Personal Information and other data we may have with appropriate governmental authorities in connection with efforts to investigate, prevent, or take other action regarding illegal activities, suspected fraud, situations involving potential threats to the physical safety of any person, or to otherwise respond to subpoenas, court orders, or legal process, requests for cooperation from law enforcement or other government agencies.

We may also provide Personal Information to a third party in connection with the sale, assignment, or other transfer of the business of this Site to which the information relates, in which case we will require any such buyer to agree to treat information in accordance with this Privacy Statement.

In addition, we may use third parties to: (a) operate and maintain the server(s) on which the Site operates, (b) provide Tracking Mechanism(s) that we embed in or use with the Site, (c) provide information to you about the Site and Services through a third party website based on a prior visit to the Site, (d) analyze communication with us, (e) de-identify data, and (f) collect non-personally identifiable information from you (e.g., on your interactions and/or experience with the Site and/or us). The third party may then share the Personal Information or other data with us.

We may be required or permitted by law to share your Personal Information, without prior notice to you, under certain circumstances including but not limited to, reporting adverse events, product recalls, preventing disease, and for health research purposes. In accordance with applicable laws and/or in a good faith effort, we may disclose your Personal Information, without prior notice to you, to maintain, safeguard, or preserve the rights or property of Lilly and UBC and to help protect the personal safety of other users of the Site, patients, and/or the general public.

Additionally, we reserve the right to disclose to third parties non-personally identifiable information collected for any lawful purpose, including but not limited to, aggregate or de-identified data.

Do Not Track
There are different ways you can prevent tracking of your online activity. One of them is setting a preference in your browser that alerts websites you visit that you do not want them to collect certain information about you. This is referred to as a Do Not Track ("DNT") signal. Please note that currently our Site and web-based resources do not track users over time and across the third party sites to provide targeted advertising, and therefore do not respond to these signals from web browsers. At this time, there is no universally accepted standard for what a company should do when a DNT signal is detected. However, you may control certain Tracking Mechanisms as described above.

Data Security
We are committed to protecting the privacy and security of this Site. We take commercially reasonable steps, including appropriate and reasonable physical, electronic and procedural safeguards, to protect Personal Information we process and maintain from loss, misuse, and unauthorized access, disclosure, alteration, or destruction. We limit access to Personal Information to authorized employees and third parties who need access to perform the business activities described in this Privacy Statement. Although we strive to protect the Personal Information we process and maintain, no security system can prevent all potential security breaches. Therefore, we do not guarantee that your Personal Information will be secure from theft, loss, or unauthorized access or use, and we make no representation as to the reasonableness, efficacy, or appropriateness of the measures we use to safeguard such Personal Information. Please keep this in mind when disclosing Personal Information to us or to any other party via the Internet.

Children
This Site is not intended for, or designed to attract, individuals under the age of 18. We do not knowingly collect Personal Information from any person under the age of 18. If we determine that such information has been inadvertently collected on or before the age of 18, we will take the necessary steps to ensure that such information is deleted from our systems. If you are a parent or guardian and become aware that your child has provided us with information, please contact us using one of the methods specified below.

More Information
Data Retention
Except to the extent prohibited by law, and subject to this Privacy Statement, we retain information collected through the Site for as long as it is necessary to provide you with the Services and comply with applicable laws, regulations, and court orders.

Links to Other Websites
As a convenience to our visitors, our Site may contain links to a number of sites owned and operated by third parties that we believe may offer useful information. The policies and procedures we describe here do not apply to those sites. Lilly or UBC is not responsible for the collection or use of information at any third party sites. We suggest contacting those sites directly for information on their privacy, security, data collection, and distribution policies.
Your Rights - General
Depending on your jurisdiction, you may have certain rights regarding our collection, use, and disclosure of your Personal Information. If you have any questions regarding these rights, please contact us.

You may be able to opt-out of certain communications by following customization and/or opt-out options. We will provide an option to unsubscribe or opt out of further communication on any electronic marketing communication sent to you or you may opt out by contacting us as set out in this Privacy Statement.

California Privacy Rights
Your Privacy Rights: California Civil Code Section 1798.83 entitles California residents who have an established business relationship with Lilly to request information regarding Lilly's disclosure of certain Personal Information to third parties for their direct marketing purposes. To make a request for such information, you may contact us in writing to: ZYPREXA RELPREVIV Patient Care Program Coordinating Center at 200 Pinecrest Plaza, Morgantown, WV 26505 or you may call 877-772-9390.

California Consumer Privacy Act (CCPA) entitles California residents to certain rights with regard to their PI. Those rights have been incorporated into this Privacy Statement.

We do not sell Personal Information. We do not share Personal Information with other people or non-affiliated businesses for their direct marketing purposes.

Information exempt from the CCPA
Note that certain information that is governed by the California Confidentiality of Medical Information Act (CMIA), HIPAA, or is subject to the Federal Policy for the Protection of Human Subjects, also known as the Common Rule, pursuant to good clinical practice guidelines issued by the International Council for Harmonisation or pursuant to human subject protection requirements of the FDA, is not considered personal information with respect to the rights of California residents noted above. However, additional rights might be available under those laws and standards.

Choices and Questions
If you provide us with Personal Information on this Site and later decide to opt-out of this decision, you may contact us as provided below. Upon verification of your identity, and as applicable by law, you also have the right to:

- request:
  - information from us on how your Personal Information is being processed, and with whom it is being shared
  - information about our process to verify your identity
  - to see and get a copy of the Personal Information that we have about you
  - that we correct, restrict the processing of, and/or erase/delete your Personal Information
  - to have your information transmitted to another entity or person in a machine-readable format, in limited circumstances
  - change or withdraw your consent at any time

There may be exceptions that apply to your request. To exercise your rights, you or your authorized representative may submit a request to: ZYPREXA RELPREVIV Patient Care Program Coordinating Center at 200 Pinecrest Plaza, Morgantown, WV 26505 or you may call 877-772-9390.

You will not be discriminated against for exercising any of your rights.

If you are receiving commercial emails from us, you may write to the address below or follow the opt-out instructions on those emails. Please note that you may continue to receive materials while we are updating our lists.

How to Contact Us
If you have any questions about this privacy policy, you may contact us at:

ZYPREXA RELPREVIV Patient Care Program Coordinating Center
200 Pinecrest Plaza
Morgantown, WV 26505
1-877-772-9390

Changes to Our Privacy Practices
We may update this Privacy Statement from time to time. When we do update it, for your convenience, we will make the updated statement available on this page. We will always handle your Personal Information in accordance with the Privacy Statement in effect at the time it was collected. We will not make any materially different use your Personal Information unless we notify you and give you an opportunity to object.

Updated [26 February 2021]
Purpose
This website has been prepared for the purpose of providing information about the Zyprexa Relprevv Patient Care Program. This site is intended for use only by residents of the United States who are age 18 or older.

This website (the "Site") is administered by staff at United Biomedical Corporation ("UBC") on behalf of its sponsor Eli Lilly and Company ("Lilly").

UBC makes information about the Zyprexa Relprevv Patient Care Program available on this Site, subject to the following Terms of Use ("Terms"). UBC reserves the right to change these Terms at any time without notice. You agree to be bound by the most recent version of the Terms posted on this Site. These Terms represent the entire understanding between you and UBC relating to the use of this Site.

Security Notice
For the purpose of maintaining security of the Site and to ensure that this service remains available to all users, UBC uses software programs to monitor network traffic to identify unauthorized attempts to upload or change information, or otherwise cause damage. Unauthorized attempts to upload information or change information on this service are strictly prohibited and may be subject to prosecution and punishable under the Computer Fraud and Abuse Act of 1986 and the National Information Infrastructure Protection Act.

General Disclaimer
While we make every effort to provide accurate and complete information, some information may change between Site updates. The information provided on this Site is provided for informational purposes only and is meant to present an overview of the training, registration process and resources available relating to the Zyprexa Relprevv Patient Care Program. The content is not intended in any way to be a substitute for professional medical advice and should not be interpreted as treatment recommendations. Only a physician who has had an opportunity to interact with the patient in person, with access to the patient's records and the opportunity to conduct appropriate follow-up, can provide recommendations for treatment.

Always seek the advice of your physician or other qualified health provider with any questions you may have regarding a medical condition. Neither the content nor any other service offered by or through this Site is intended to be relied on for medical diagnosis or treatment, without a physician's interaction and involvement. Never disregard medical advice or delay in seeking it because of something you have read on this Site.

Warranties and Disclaimers
UBC may change any information on this Site or any product or service described on this Site, including functionality or performance, at any time without notice. UBC does not guarantee freedom from computer viruses, worms or other malicious software, and makes no representation that use of this Site does not infringe on any privately owned rights of a third party.

THE SITE AND THE CONTENT ARE PROVIDED "AS IS". UBC AND LILLY, TO THE FULLEST EXTENT PERMITTED BY LAW, DISCLAIM ALL WARRANTIES, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OF THIRD PARTY RIGHTS, AND FITNESS FOR PARTICULAR PURPOSE.

IN NO EVENT WILL UBC OR LILLY BE LIABLE FOR ANY DAMAGE WHATSOEVER (INCLUDING WITHOUT LIMITATION DAMAGES RELATING TO LOST REVENUES OR PROFITS, LOST DATA, WORK STOPPAGE, COMPUTER FAILURE OR MALFUNCTION) RESULTING FROM OR ARISING IN ANY WAY RELATED TO THE USE OF ANY MATERIALS POSTED ON OR MADE AVAILABLE AT THIS SITE OR ANY OTHER SITE TO WHICH A LINK IS PROVIDED OR ON WHICH A LINK IS PROVIDED TO THIS SITE, REGARDLESS OF THE LEGAL THEORY ON WHICH SUCH DAMAGES ARE BASED.

No Endorsement
Reference in this Site to any specific commercial products, processes, or services, or the use of any trade, firm or corporation name is for the information and convenience of the Site's visitors, and does not constitute an endorsement or recommendation by UBC.

Links to Other Websites
This Site may contain links to other websites that are not hosted by UBC. These websites are not under the control of UBC, and UBC is not responsible for their content or the content of any information linked to these websites. Links to other websites, if any, are provided as a convenience to our users and do not imply any endorsement by UBC of information contained in those websites or the organizations that support them.

Privacy
Please see our Privacy Statement for information on how we protect personal information you provide to us.

For More Information
If you have any questions or comments about the information presented here, please contact UBC at Phone: 1-877-772-9396, Fax: 1-877-772-9191.

Reference ID: 4786995
This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

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