

**Title: ZYPREXA RELPREVV Reconstitution and Administration Training Video**

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

**ZYPREXA RELPREVV**  
Reconstitution and Administration Training Video



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

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VIDEO	AUDIO
<b>Introduction</b>	
<p><b>Text on-screen:</b> ZYPREXA RELPREVV logo</p> <p>ZYPREXA RELPREVV Reconstitution and Administration Training</p>	<i>Music</i>
<p><b>Text on-screen:</b> ZYPREXA RELPREVV logo Chapter One: Introduction</p>	<i>Music</i>
<p><b>Text on-screen:</b> ZYPREXA RELPREVV (olanzapine) For Extended Release Injectable Suspension is an antipsychotic agent indicated for the treatment of schizophrenia in adults.</p>	<i>Music</i>
<p><b>Text on-Screen:</b> All healthcare professionals who administer this product must view this video before giving an injection of ZYPREXA RELPREVV.</p> <p>For important safety Information, including boxed warnings, see the full prescribing information provided.</p>	All healthcare professionals who administer this product must view this video before giving an injection of ZYPREXA RELPREVV.
<p><b>Visual:</b> Nurse (talent) talking to camera</p>	ZYPREXA RELPREVV is a long acting injectable formulation of olanzapine. It is indicated for the treatment of schizophrenia in adults. The efficacy of ZYPREXA RELPREVV is consistent with the established efficacy of orally administered Zyprexa for treatment of schizophrenia in adults.
<p><b>Text on-Screen:</b> Vial Strengths: • 210-mg, 300-mg, and 405-mg</p> <p>Dosing Schedules: • Every 2 weeks: 150-mg, 210-mg, or 300-mg • Every 4 weeks: 300-mg or 405-mg</p>	ZYPREXA RELPREVV is available in 210-, 300-, and 405-milligram vials. It may be administered every 2 weeks in 150-mg, 210-mg, or 300-mg doses, or every 4 weeks in 300-mg or 405-mg doses.
<p><b>Visual:</b> Nurse talking to camera</p>	The purpose of this video is to teach you how to properly reconstitute and administer ZYPREXA RELPREVV.
<p><b>Text on-Screen:</b></p> <ul style="list-style-type: none"> <li>• Description of Post-Injection Delirium/Sedation Syndrome</li> <li>• Demonstration of ZYPREXA RELPREVV product reconstitution</li> <li>• Demonstration of injection technique</li> <li>• Real-time demonstration of reconstitution and administration process</li> </ul>	<p>First we will begin by explaining the Post-Injection Delirium/Sedation Syndrome events that occurred with ZYPREXA RELPREVV in pre-marketing clinical trials.</p> <p>Then, we will demonstrate step-by-step instructions on how to properly reconstitute the product.</p> <p>Once it has been reconstituted, we will show you the proper administration techniques and demonstrate the entire reconstitution and administration process in real time.</p>

<p><b>Visual:</b> Nurse talking to camera</p>	<p>Please watch the end of this video and see accompanying full prescribing information for important safety information including boxed warnings.</p>								
<b>Post-Injection Delirium/Sedation Syndrome</b>									
<p><b>Text on-screen:</b> ZYPREXA RELPREVV logo</p> <p>Chapter Two: Post-Injection Delirium/Sedation Syndrome</p>	<p><i>Music</i></p>								
<p><b>Visual:</b> Nurse talking to camera</p>	<p>During pre-marketing clinical studies, events that presented with signs and symptoms consistent with olanzapine overdose were reported in some patients following an injection of ZYPREXA RELPREVV.</p>								
<p><b>Text on screen:</b> Events occurred:</p> <ul style="list-style-type: none"> <li>• in &lt; 0.1% of injections</li> <li>• in approximately 2% of patients</li> </ul>	<p>These events occurred in &lt;0.1% of injections and in approximately 2% of patients who received injections for up to 46 months.</p>								
<p><b>Text on screen:</b> Symptoms:</p> <ul style="list-style-type: none"> <li>• Sedation: ranging from mild in severity up to coma</li> <li>• Delirium: confusion, disorientation, agitation, anxiety, other cognitive impairment</li> <li>• Other Symptoms: extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension, possible convulsion</li> </ul>	<p>Most of these patients developed symptoms of sedation, ranging from mild in severity up to coma, and/or delirium, including confusion, disorientation, agitation, anxiety and other cognitive impairment. Other symptoms noted included extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension or possible convulsion.</p>								
<p><b>Text on screen:</b> PDSS Symptom Onset:</p> <table border="1" data-bbox="191 1115 557 1318"> <thead> <tr> <th style="background-color: #8B4513; color: white;">Time of Onset of Symptoms</th> <th style="background-color: #8B4513; color: white;">Patients</th> </tr> </thead> <tbody> <tr> <td>&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>	Time of Onset of Symptoms	Patients	<60 min	~ 80%	1 to 3 hours	~ 14%	>3 hours	~ 6%	<p>In pre-marketing clinical trials, the potential for onset of a PDSS event was greatest within the first hour. The majority of cases have occurred within the first 3 hours after injection; however the event has occurred after 3 hours.</p>
Time of Onset of Symptoms	Patients								
<60 min	~ 80%								
1 to 3 hours	~ 14%								
>3 hours	~ 6%								
<p><b>Visual:</b> Nurse talking to camera</p> <p><b>Text on screen:</b></p> <ul style="list-style-type: none"> <li>• Observe patients for 3 hours for symptoms of PDSS</li> </ul>	<p>Patients should be advised of this potential risk and the need to be observed for 3 hours in a healthcare facility each time ZYPREXA RELPREVV is administered.</p> <p>Patients experiencing post-injection delirium/sedation syndrome should be managed as clinically appropriate. Patients may be treated symptomatically.</p> <p>If a Post-injection Delirium/Sedation Syndrome event is suspected, close medical supervision and monitoring should be conducted in a facility capable of resuscitation.</p>								
<p><b>Text on screen:</b> If parenteral benzodiazepines are required for patient management during a PDSS event, careful evaluation of clinical status for excessive sedation and cardiorespiratory depression is recommended.</p>	<p>If parenteral benzodiazepines are required for patient management during a PDSS event, careful evaluation of clinical status for excessive sedation and cardiorespiratory depression is recommended.</p>								

<p><b>Text on screen:</b> Notify hospital or ER personnel of:</p> <ul style="list-style-type: none"> <li>• "...a probable olanzapine overdose following administration of Olanzapine For Extended Release Injectable Suspension."</li> </ul>	<p>If the patient is sent to a hospital or ER for further observation or management, notify the hospital or ER personnel that the patient is experiencing "a probable olanzapine overdose following administration of Olanzapine For Extended Release Injectable Suspension."</p>
<p><b>Text on screen:</b> Important: Before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection.</p>	<p>An important reminder: before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection.</p>
<p><b>Text on-Screen:</b> After each injection:</p> <ul style="list-style-type: none"> <li>• Patients should be observed for at least 3 hours by appropriately qualified personnel in a healthcare facility with ready access to emergency response services</li> <li>• The patient should be located where he or she can be seen and/or heard at all times</li> </ul>	<p>After each ZYPREXA RELPREVV injection:</p> <ul style="list-style-type: none"> <li>• Patients should be observed for at least 3 hours by appropriately qualified personnel in a healthcare facility with ready access to emergency response services</li> <li>• The patient should be located where he or she can be seen and/or heard at all times</li> </ul>
<p><b>Text on-Screen:</b> Before patient leaves the healthcare facility:</p> <ul style="list-style-type: none"> <li>• Confirm that the patient is alert, oriented, and without signs or symptoms of a post-injection delirium/sedation syndrome event</li> <li>• 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</li> <li>• All patients should be accompanied to their next destination upon leaving the facility</li> </ul>	<p>Before the patient leaves the healthcare facility:</p> <ul style="list-style-type: none"> <li>• Confirm that the patient is alert, oriented, and without signs or symptoms of a post-injection syndrome event</li> <li>• Advise patients and their caregivers to be vigilant for symptoms of a post-injection syndrome event for the remainder of the day and be able to obtain assistance if needed</li> <li>• All patients should be accompanied to their next destination upon leaving the facility</li> </ul>
<p><b>Text on-Screen:</b> After patient leaves the healthcare facility:</p> <ul style="list-style-type: none"> <li>• Patients should not drive or operate heavy machinery for the remainder of the day</li> </ul>	<p>After leaving the healthcare facility, patients should not drive or operate heavy machinery for the remainder of the day.</p>
<p><b>Visual:</b> Nurse talking to camera</p>	<p>In addition, patient ID cards and wristbands are available for distribution to patients who receive ZYPREXA RELPREVV. The patient ID cards can be used to record the date and time of injection, concomitant medications, and emergency contact information. The wristbands can be used to note the date of the injection and an emergency contact number. Please contact your Lilly sales representative to receive a supply of patient ID cards and wristbands to use in your treatment facility.</p>

<p><b>Text on-Screen:</b> Increased contact with blood can occur:</p> <ul style="list-style-type: none"> <li>• Partial injection into vasculature</li> <li>• Significant vessel injury during IM injection (nick or puncture)</li> <li>• Substantial bleeding at injection site</li> </ul>	<p>ZYPREXA RELPREVV is much more soluble in blood than in muscle. Increased contact with a substantial volume of blood could occur in several ways, such as:</p> <ul style="list-style-type: none"> <li>• Partial injection into vasculature</li> <li>• Vessel injury associated with the intramuscular injection (a nick or puncture of the blood vessel)</li> <li>• And substantial bleeding at injection site</li> </ul>
<p><b>Text on-Screen:</b> Deep intramuscular gluteal injection:</p> <ul style="list-style-type: none"> <li>• Intended for deep muscular gluteal injection only <ul style="list-style-type: none"> <li>○ Not for intravenous, subcutaneous, or deltoid injection</li> </ul> </li> <li>• Aspirate syringe prior to injection to ensure no blood is visible</li> <li>• If blood is visible, discard the syringe and use a new product kit</li> </ul>	<p>Therefore, ZYPREXA RELPREVV is intended for deep intramuscular gluteal injection only. It is important to aspirate the syringe prior to injection to ensure no blood is visible. Administrators must not proceed with the injection if blood is visible. If blood is visible, discard the syringe and use a new product kit.</p>
<p><b>Visual:</b> Nurse talking to camera</p> <p><b>Text on screen:</b></p> <ul style="list-style-type: none"> <li>• Post-Injection Delirium/Sedation Syndrome can occur at any injection</li> </ul>	<p>Post-injection Delirium/Sedation Syndrome can occur at any injection, so safety precautions should be observed every time the product is administered.</p>
<p><b>Step 1 – Prepare Materials</b></p>	
<p><b>Text on screen:</b> ZYPREXA RELPREVV logo</p> <p>Chapter Three Step 1 – Prepare Materials</p>	<p>Music</p>
<p><b>Visual:</b> Nurse talking to camera</p>	<p>Let's begin by preparing for the ZYPREXA RELPREVV injection.</p>
<p><b>Visual:</b> Pair of hands placing gloves and alcohol wipes on counter.</p>	<p>First, you will need to gather and prepare your materials.</p> <p>Obtain 1 pair of gloves, several alcohol wipes, and the prescribed dose of ZYPREXA RELPREVV.</p>
<p><b>Visual:</b> Nurse talking to camera</p>	<p>The medication comes packaged in a convenience kit that includes the following items:</p>
<p><b>Visual:</b> Pair of hands placing contents of kit (vial of powder, vial of diluent, Needle-Pro® 3ml syringe with safety needle, 2 additional safety needles) on counter.</p>	<p>A vial of ZYPREXA RELPREVV powder; a 3ml vial of diluent, one Needle-Pro® 3ml syringe with attached 19 gauge, 1.5 inch safety needle, 2 additional 19 gauge, 1.5 inch safety needles, a Reconstitution and Administration leaflet, and a patient Medication Guide.</p>
<p><b>Visual:</b> Nurse talking to camera</p>	<p>Open the kit, remove all items, and arrange them conveniently to prepare for reconstitution</p>
<p><b>Visual:</b> Pair of hands putting on gloves</p>	<p>You will need to wear gloves when reconstituting ZYPREXA RELPREVV, as the medication can be irritating to the skin.</p>
<p><b>Visual:</b> Nurse talking to camera</p>	<p>If the medication contacts skin, flush it with water.</p>

<b>Step 2 – Determine Reconstitution Volume</b>	
<p><b>Text on screen:</b> ZYPREXA RELPREVV logo</p> <p>Chapter Four Step 2 – Determine Reconstitution Volume</p>	Music
<p><b>Visual:</b> Nurse talking to camera</p>	Next you will need to determine the reconstitution volume.
<p><b>Visual:</b> C/U of table on reconstitution and administration instructions</p>	Please refer to the table in the full-color reconstitution and administration instructions for the proper volumes of diluent to add for each vial strength. For example, if you are preparing a 210mg dose, you will need to add 1.3ml of diluent to the 210mg powder vial.
<p><b>Visual:</b> Nurse talking to camera</p> <p><b>Text on-screen:</b> There will be excess diluent remaining in the vial</p>	It is important to note that no matter what dose you are preparing, there will be excess diluent remaining in the vial. This extra diluent will not be needed.
<b>Reconstitute</b>	
<p><b>Text on screen:</b> ZYPREXA RELPREVV logo</p> <p>Chapter Five Reconstitute</p>	Music
<p><b>Visual:</b> Nurse talking to camera</p>	Now you are ready to reconstitute ZYPREXA RELPREVV. The process of reconstitution and administration should take around 5 minutes to complete.
<p><b>Visual:</b> Hands tapping powder vial and wiping vials with alcohol wipes</p>	First, loosen the powder by lightly tapping the vial a few times. The powder should be free flowing. This step helps to ensure the powder suspends easily and thoroughly after the diluent is added.
<p><b>Visual:</b> Hands withdrawing diluent into syringe</p>	Withdraw the proper amount of diluent into the syringe. In this case, the vial strength is 210mg, so we will withdraw 1.3ml of solution.
<p><b>Visual:</b> Hands injecting diluent into powder vial</p>	Inject the diluent into the powder vial. Before you withdraw the needle, pull back on the plunger to withdraw some air. This will help equalize pressure in the vial. Hold the vial upright when removing the needle to prevent any loss of medication. Next, engage the safety needle and push the air out of the syringe.
<p><b>Visual:</b> Hands tapping the vial</p> <p><b>Text on screen:</b> • Tap firmly and repeatedly</p>	The suspension must be mixed correctly to ensure proper dosing. Tap the vial firmly and repeatedly on a hard, cushioned surface until there is no powder visible. Avoid shaking the vial before tapping, as this can make it more difficult to suspend.
<p><b>Visual:</b> Hands tap and shake vial</p>	Check for clumps by inspecting the sides and bottom of the vial. Unsuspended powder appears as light yellow, dry clumps clinging to the vial.

<p><b>Visual:</b> C/U of suspension</p>	<p>If clumps are visible, tap the vial again to break the clumps free. Shake the vial vigorously until the suspension appears smooth and consistent in color and texture.</p>
<p><b>Visual:</b> Hands continue to shake, tap and inspect vial</p>	<p>Sometimes foam will form from shaking the vial. The foam will dissipate if you let the vial stand briefly. You should avoid drawing foam up into the syringe, as the excess air bubbles are hard to remove and may affect the accuracy of the dose.</p>
<p><b>Visual:</b> Nurse talking to camera</p> <p><b>Text on screen:</b> Product is stable in the vial for 24 hours after reconstitution.</p>	<p>Once reconstituted, the suspension is stable in the vial for up to 24 hours and does not require refrigeration. However, if the suspension is not used immediately, it should be shaken to resuspend before being drawn into the syringe for administration. Once drawn up into the syringe, this medication should be injected immediately.</p>
<p>Inject ZYPREXA RELPREVV</p>	
<p><b>Text on screen:</b> ZYPREXA RELPREVV logo</p> <p>Chapter Six Inject ZYPREXA RELPREVV</p>	<p><i>Music</i></p>
<p><b>Visual:</b> Hands attaching new safety needle</p>	<p>Attach a new safety needle to the syringe.</p> <p>For all doses, the concentration of olanzapine in the suspension is 150 mg per 1 ml.</p>
<p><b>Visual:</b> C/U of table of instructions</p>	<p>When preparing to draw up the prescribed dose, refer to the table in the instructions for the correct injection volume.</p> <p>For a prescribed dose of 210mg, you will withdraw 1.4ml from the reconstituted vial.</p>
<p><b>Visual:</b> C/U of hands withdrawing suspension into the syringe</p>	<p>To prevent the product from leaking from the stopper, do not add air to the vial. Slowly withdraw the desired amount into the syringe. By doing this slowly, you will avoid excess air bubbles being drawn into the syringe.</p>
<p><b>Visual:</b> Nurse talking to camera</p> <p><b>Text on screen:</b> There will be excess medication remaining in the vial</p>	<p>There will be excess medication remaining in the vial.</p>
<p><b>Visual:</b> Hands tapping syringe</p>	<p>To ensure the full dose is given, tap the syringe with your fingers to remove all excess air bubbles.</p>
<p><b>Visual:</b> Hands removing needle from vial, engaging safety device, and attaching new safety needle</p>	<p>Once the desired dose is withdrawn, remove the needle from the vial, and engage the needle safety device.</p> <p>Attach a new safety needle to the syringe.</p>

<p><b>Text on screen:</b> Important: Prior to administration, you must make sure that the patient receiving ZYPREXA RELPREVV will be accompanied to his or her destination following the 3-hour observation period.</p> <p>If this cannot be confirmed, do not give the injection.</p>	<p>Prior to administration, you must make sure that the patient receiving ZYPREXA RELPREVV will be accompanied to his or her destination following the 3-hour observation period. If this cannot be confirmed, do not give the injection.</p>
<p><b>Text on screen:</b> Important: The patient may not drive to his or her destination for the rest of the day.</p>	<p>Even if accompanied, the patient may not drive to his or her destination or for the rest of the day of injection.</p>
<p><b>Visual:</b> C/U of syringe</p>	<p>Now you are ready to give the injection of ZYPREXA RELPREVV. Once the medication is drawn into the syringe, it should be injected immediately.</p>
<p><b>Visual:</b> Nurse talking to camera</p> <p><b>Text On-Screen:</b> Do not inject the medication intravenously or subcutaneously</p>	<p>First, select and prepare a site for injection. This injection can be given in the ventrogluteal or the dorsogluteal muscle. These two areas have large muscle density and are clinically appropriate sites for deep gluteal injections.</p>
<p><b>Visual:</b> C/U of anatomical model and hands giving injection</p>	<p>For these demonstrations, we are using an anatomical model. The model is not designed to receive product, so we will be using an empty syringe to show how the injection should be administered.</p>
<b>Ventrogluteal Injection</b>	
<p><b>Text on screen:</b> ZYPREXA RELPREVV logo</p> <p>Chapter Seven Ventrogluteal Injection</p>	<p><i>Music</i></p>
<p><b>Visual:</b> C/U of practice ventrogluteal injection process on anatomical model</p>	<p>To give a ventrogluteal injection, place the heel of your hand on the greater trochanter, or hip bone at the top of the thigh. Your wrist will be in line with the person's thigh.</p> <p>Point your thumb at the groin and fingers towards the person's head. Form a "V" by opening a space between your pointer finger and the other three fingers. The place to give the injection is in the middle of the V-shaped triangle.</p> <p>Insert the needle into the muscle, then aspirate slowly for several seconds by pulling back on the plunger of the syringe.</p>
<p><b>Visual:</b> Nurse talking to camera</p>	<p>If any blood is drawn into the syringe, discard the syringe and the dose, and begin with a new kit.</p>
<p><b>Visual:</b> C/U on hands giving injection</p>	<p>In this case, no blood is seen, so we will inject the medication with steady pressure.</p>

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

<p><b>Text on-screen:</b></p> <ul style="list-style-type: none"> <li>• Prepare Materials</li> <li>• Determine Reconstitution Volume</li> <li>• Reconstitute</li> <li>• Inject</li> </ul>	<p>One, prepare materials; two, determine reconstitution volume; three, reconstitute; and four, inject.</p>
<p><b>Visual:</b> Nurse talking to camera</p>	<p><b>Narrator:</b> Watch as we demonstrate the entire process in real time. Remember, for these demonstrations, we are using an anatomical model. The model is not designed to receive product, so we will be using an empty syringe to show how the injection should be administered.</p>
<p><b>Visual:</b> Real-time reconstitution process with timer</p>	<p><i>Music</i></p>
<p><b>Text on Screen:</b> 1-800-LillyRx (1-800-545-5979) <a href="http://www.ZyprexaRelprevv.com">www.ZyprexaRelprevv.com</a></p>	<p>If you have any questions about reconstituting and administering ZYPREXA RELPREVV please contact the number on-screen or visit the following website.</p>

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# PATIENT REGISTRATION FORM



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

## PATIENT INFORMATION

First Name: \_\_\_\_\_ MI: \_\_\_\_\_ Last Name: \_\_\_\_\_

Date of Birth: \_\_\_\_\_

Gender:  Male  Female

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

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

## PRESCRIBER INFORMATION

First Name: \_\_\_\_\_ MI: \_\_\_\_\_ Last Name: \_\_\_\_\_

License Number: \_\_\_\_\_ State of Issue: \_\_\_\_\_

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

Address Line 1: \_\_\_\_\_

Address Line 2: \_\_\_\_\_

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

Yes

No (If No, complete next section)

## INJECTING/MONITORING FACILITY INFORMATION

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

Address Line 1: \_\_\_\_\_

Address Line 2: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

PHONE 1-877-772-9390

FAX 1-877-772-9391

www.zyprexarelprevvprogram.com

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PATIENT AGREEMENT

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

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

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

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

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

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

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

Signature

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

Printed Name of Patient

Printed Name of Legal Guardian (if applicable)

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

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

Signature of Prescriber

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

Printed Name of Prescriber

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# SINGLE PATIENT INJECTION FORM



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

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

Patient No.: (PIN)

Injection Facility Name:

Patient Name: \_\_\_\_\_  
 First MI Last

Date of Birth:   -   -      
 month day year

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

No  Yes

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

Yes  No

## ZYPREXA RELPREVV TREATMENT

Date of Injection:   -   -      
 month day year

Time of ZYPREXA RELPREVV injection:   :    
 24-hour clock

Dose of Injection:  150 mg  210 mg  300 mg  405 mg  Other dose \_\_\_\_\_ mg

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

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

No  Yes

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

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

Yes  No

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

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

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

Healthcare Facility Staff Member Signature \_\_\_\_\_ DATE:   -   -      
 month day year

Healthcare Facility Staff Member Name (print): \_\_\_\_\_

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# MULTIPLE PATIENT INJECTION FORM

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      month      day      year  
  -   -

	Patient Info.	Patient Info.	Patient Info.
Patient No.: (PIN)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Patient Name:	First Name _____ MI _____ Last Name _____	First Name _____ MI _____ Last Name _____	First Name _____ MI _____ Last Name _____
Date of Birth:	mon h - day - year ____ - ____ - ____	month - day - year ____ - ____ - ____	month - day - year ____ - ____ - ____
PDSS since last visit? (check one)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> No
Time of Injection (24-hour clock)	<input type="text"/> : <input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/> : <input type="text"/>
Dose of Injection (check one)	<input type="checkbox"/> 150 mg <input type="checkbox"/> 210 mg <input type="checkbox"/> 300 mg <input type="checkbox"/> 405 mg <input type="checkbox"/> Other dose _____ mg	<input type="checkbox"/> 150 mg <input type="checkbox"/> 210 mg <input type="checkbox"/> 300 mg <input type="checkbox"/> 405 mg <input type="checkbox"/> Other dose _____ mg	<input type="checkbox"/> 150 mg <input type="checkbox"/> 210 mg <input type="checkbox"/> 300 mg <input type="checkbox"/> 405 mg <input type="checkbox"/> Other dose _____ mg
Observed at least 3 hours post-injection? (check one)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
PDSS during onsite observation? (check one)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, has the prescriber been notified of the PDSS event? <input type="checkbox"/> Yes <input type="checkbox"/> No
Following the injection, was the patient alert, oriented, and absent of any signs and symptoms of PDSS prior to being released from the healthcare facility? (check one)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Following the injection, was the patient accompanied from the facility? (check one)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable, patient did not leave facility (in-patient)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable, patient did not leave facility (in-patient)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable, patient did not leave facility (in-patient)
Signature	Healthcare Facility Staff Member Signature _____ <input type="text"/> - <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> month      day      year Healthcare Facility Staff Member Name (print)	Healthcare Facility Staff Member Signature _____ <input type="text"/> - <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> month      day      year Healthcare Facility Staff Member Name (print)	Healthcare Facility Staff Member Signature _____ <input type="text"/> - <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> month      day      year Healthcare Facility Staff Member Name (print)
Was the patient or legal guardian given a Medication Guide prior to this injection?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

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# POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM



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

Patient No.: (PIN)

Patient Name: \_\_\_\_\_  
First Name MI Last Name

Date of Birth:   -   -      
month day year

Does the patient have a diagnosis of schizophrenia?  Yes  No

## PATIENT/INJECTION INFORMATION

Date of Injection:   -   -      
month day year

Convenience Kit Package

Lot # \_\_\_\_\_

Time of ZYPREXA RELPREVV Injection:   :    
24-hour clock

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

- |  |  |   |
|--|--|---|
| <input type="checkbox"/> 1 - 15 minutes  | <input type="checkbox"/> 46 - 60 minutes             | <input type="checkbox"/> 121 - 150 minutes (2 ½ hours)                          |
| <input type="checkbox"/> 16 - 30 minutes | <input type="checkbox"/> 61 - 90 minutes (1 ½ hours) | <input type="checkbox"/> 151 - 180 minutes (3 hours)                            |
| <input type="checkbox"/> 31 - 45 minutes | <input type="checkbox"/> 91 - 120 minutes (2 hours)  | <input type="checkbox"/> If greater than 3 hours please specify:<br>_____ Hours |

Dose of Injection:  150 mg  210 mg  300 mg  405 mg  Other dose \_\_\_\_\_ mg

Was the injection given in gluteal muscle?  Yes  No

Height: (inches)     Weight: (lbs.)

## PDSS SIGNS AND SYMPTOMS

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

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

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# POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.: (PIN)

Patient Name: \_\_\_\_\_  
First Name MI Last Name

PDSS start date:   -   -     
month day year

PDSS resolution date:   -   -    OR  Ongoing  
month day year

If resolved, duration of PDSS: \_\_\_\_\_  Minutes  Hours  Days

Are these PDSS symptoms related to ZYPREXA RELPREVV?

Yes

No - Please Explain \_\_\_\_\_  
\_\_\_\_\_

Describe the clinical course \_\_\_\_\_  
\_\_\_\_\_

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

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

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

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

Were olanzapine concentrations collected?  Yes  No

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

Treatment Medication Name	Dose	Duration of Use (in Days)

# POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.: (PIN)

Patient Name: \_\_\_\_\_  
First Name MI Last Name

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

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

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

## HISTORY PRIOR TO PDSS EVENT

Does the patient have any relevant comorbidities?

- Yes - Please specify: \_\_\_\_\_
- No

## PRIOR MEDICATIONS

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

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

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

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

Event reported by: \_\_\_\_\_  
First MI Last

Title/Occupation: \_\_\_\_\_

If agent of the Prescriber, name of Prescriber: \_\_\_\_\_

