



# ZYPADHERA

*olanzapine powder & solvent for prolonged  
release suspension for injection*

## Reconstitution Training for Healthcare Professionals

*Lilly*

# Reconstitution Training for Healthcare Professionals

## ➤ Training Objectives

- Know what materials are available in convenience kit
- Determine what volume is needed for reconstitution
- Learn the steps to reconstitute the material
- Understand the steps required for injecting ZYPADHERA

## ➤ General Process

- Reconstitution
  - Materials
  - Determining volume
  - Reconstituting ZYPADHERA
- Administration
- Safety Information About Needles

# Reconstitution

## STEP 1: Preparing materials

Pack includes:

- Vial of ZYPADHERA powder for prolonged release suspension for injection
- Vial of solvent for ZYPADHERA
- One Hypodermic syringe with pre-attached 19-gauge, 38 mm safety needle (Hypodermic Device)
- One 19-gauge, 38 mm safety needle
- Two 19-gauge, 50mm safety needles (For obese patients, 19-gauge, 50 mm needles are recommended for injection)



- **It is recommended that gloves are used as ZYPADHERA may irritate the skin.**
- Reconstitute ZYPADHERA powder for prolonged release suspension for injection only with the solvent provided in the pack using standard aseptic techniques for reconstitution of parenteral products.

## *Reconstitution*

### **STEP 2: Determining solvent volume for reconstitution**

This table provides the amount of solvent required to reconstitute ZYPADHERA powder for prolonged release suspension for injection.

<b>ZYPADHERA vial strength (mg)</b>	<b>Volume of solvent to add (ml)</b>
<b>210</b>	<b>1.3</b>
<b>300</b>	<b>1.8</b>
<b>405</b>	<b>2.3</b>

It is important to note that there is more solvent in the vial than is needed to reconstitute.

# Reconstitution

## STEP 3: Reconstituting ZYPADHERA

- Loosen the powder by lightly tapping the vial.
- **Open the pre-packaged Hypodermic syringe and needle with needle protection device.**
- Withdraw the pre-determined solvent volume (Step 2) into the syringe.
- Inject the solvent volume into the powder vial.
- Withdraw air to equalize the pressure in the vial.
- Remove the needle, holding the vial upright to prevent any loss of solvent.
- Engage the needle safety device.
- Tap the vial firmly and repeatedly on a hard surface until no powder is visible. Protect the surface to cushion impact. (See Figure A)

**Figure A: Tap firmly to mix**



# Reconstitution

## STEP 3: Reconstituting ZYPADHERA

- Visually check the vial for clumps. Unsuspended powder appears as yellow, dry clumps clinging to the vial. Additional tapping may be required if clumps remain. (See Figure B)



**Unsuspended: visible clumps**



**Suspended: no clumps**

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

## *Reconstitution*

### **STEP 3: Reconstituting ZYPADHERA**

- Shake the vial vigorously until the suspension appears smooth and is consistent in color and texture. The suspended product will be yellow and opaque. (See Figure C)



**Figure C: Vigorously shake vial**

If foam forms, let vial stand to allow foam to dissipate. If the product is not used immediately, it should be shaken vigorously to re-suspend.

# *Administration*

## **STEP 1: Injecting ZYPADHERA**

This table confirms the final ZYPADHERA suspension volume to inject.

<b>Dose (mg)</b>	<b>ZYPADHERA vial strength (mg)</b>	<b>Final volume to inject (ml)</b>
<b>150</b>	<b>210</b>	<b>1.0</b>
<b>210</b>	<b>210</b>	<b>1.4</b>
<b>300</b>	<b>300</b>	<b>2.0</b>
<b>405</b>	<b>405</b>	<b>2.7</b>

Suspension concentration is 150 mg/ml olanzapine.



# Administration

## STEP 1: Injecting ZYPADHERA

- Determine which needle will be used to administer the injection to the patient. For obese patients, the 2-inch [50 mm] needle is recommended for injection.
  - If the 2-inch [50 mm] needle is to be used for injection, attach the 1.5-inch [38 mm] safety needle to the syringe to withdraw the required suspension volume.
  - If the 1.5-inch [38 mm] needle is to be used for the injection, attach the 2-inch [50 mm] safety needle to the syringe to withdraw the required suspension volume.
- Slowly withdraw the desired amount. Some excess product will remain in the vial.
- Engage the needle safety device and remove needle from syringe.
- **Attach the selected 50 mm or 38 mm safety needle to the syringe prior to injection. Once the suspension has been removed from the vial, it should be injected immediately.**
- Select and prepare a site for injection in the gluteal area.

**FOR DEEP INTRAMUSCULAR GLUTEAL INJECTION ONLY.**

**DO NOT ADMINISTER INTRAVENOUSLY OR SUBCUTANEOUSLY.**

# Administration

## STEP 1: Injecting ZYPADHERA

- After insertion of the needle, aspirate for several seconds to ensure no blood appears.
  - If any blood is drawn into the syringe, discard the syringe and the dose and begin reconstitution and administration procedure again.
- The injection should be performed with steady, continuous pressure  
**DO NOT MASSAGE THE INJECTION SITE.**
- Engage the needle safety device.
- Discard the vials, syringe, used needles, extra needle and any unused solvent in accordance with appropriate clinical procedures. The vial is for single use only.

## *SAFETY INFORMATION ABOUT THE NEEDLES*

# Needle Sticks and Damaged Needles

- A needle stick with a contaminated needle may cause infectious disease.
- Intentional disengagement of the **hypodermic safety** device may result in a needle stick with a contaminated needle.
- Bent or damaged needles can result in breakage or damage to the tissue or accidental needle puncture.
- If the needle is bent or damaged, no attempt should be made to straighten the needle or engage the **hypodermic safety** device.

## *SAFETY INFORMATION ABOUT THE NEEDLES*

# Needle Sticks and Damaged Needles

- The **hypodermic safety** device may not properly contain a bent needle and/or the needle could puncture the needle protection device, which may result in a needle stick with a contaminated needle.
- Mishandling of the needle protection device may cause needles, to bend whereby they protrude from the needle protector sheath, which may result in a contaminated needle stick.
- Do not use the needle with paraldehyde.

# SAFETY INFORMATION ABOUT THE NEEDLES

## Instructions for Use

- Peel blister pouch and remove device.
- Insure needle is firmly seated on the **hypodermic safety** device with a push and a clockwise twist, then pull the needle cap straight away from the needle.
- After procedure is completed, press the needle into the sheath using a one-handed technique.
- Perform a one-handed technique by GENTLY pressing the sheath against a flat surface.
- AS THE SHEATH IS PRESSED, THE NEEDLE IS FIRMLY ENGAGED INTO THE SHEATH
- Visually confirm that the needle is fully engaged into the needle protection sheath



***Firmly press needle into sheath.***

- Only remove the **hypodermic safety** device with the engaged needle from the syringe when required by a specific medical procedure.
- Remove by grasping the Luer hub of the needle protection device with thumb and forefinger, keeping the free fingers clear of the end of the device containing the needle point.