



## **Reconstitution Training for Healthcare Professionals**

# Reconstitution Training for Healthcare Professionals

## ➤ **Training Objectives**

- Know what materials are available in convenience pack
- Determine what volume is needed for reconstitution
- Learn the steps to reconstitute the drug
- Understand the steps required for injecting ZYPADHERA
- Understand safety precautions required for each ZypAdhera injection.

## ➤ **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 colour 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 pamoate.



## **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.**

## **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 safety device may cause needles to bend whereby they protrude from the needle safety device, 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.
- Ensure needle is firmly seated on the hypodermic safety device with a push and a clockwise twist, then pull the needle safety device 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 safety device



***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 safety device with thumb and forefinger, keeping the free fingers clear of the end of the device containing the needle point.

# Safety Precautions

## With each ZYPADHERA injection -

### After the injection:

- Patients should be observed in a healthcare facility by appropriately qualified personnel for at least 3 hours.
  - The patient should be located where he can be seen and/or heard.
  - At least hourly checks for signs of a post injection syndrome event are recommended.

### Immediately prior to leaving the healthcare facility:

- Confirm that the patient is alert, oriented, and without signs or symptoms of a post injection syndrome event.
- Advise patients 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.

### After leaving the healthcare facility:

- Patients should not drive or operate machinery for the remainder of day.

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