ZYPAdhera™

Olanzapine Powder and Solvent for Prolonged Release Suspension for Injection

Reconstitution Training for Healthcare Professionals

CHEPLA PHARM

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.

ZYPADHERA vial strength (mg)	Volume of solvent to add (ml)
210	**1.3**
300	**1.8**
405	**2.3**

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

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.

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.

STEP 1: Injecting ZYPADHERA

This table confirms the final ZYPADHERA suspension volume to inject.

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

Suspension concentration is 150 mg/ml olanzapine pamoate.

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 ADMINSTER 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.

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.

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 <u>each</u> 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.

Brunner, et al. Presented at APA 2009, San Francisco, CA, USA
Gulliver, McDonnell, Sorsaburu, et al. *Int J Neuropsychopharmacol* 2008; 11(suppl 1):152.
ZYPADHERA SPC: http://www.medicines.org.uk/EMC/medicine/21361/SPC/ZYPADHERA