INSTRUCTIONS FOR HEALTH CARE PROFESSIONALS

RECONSTITUTION AND ADMINISTRATION INSTRUCTIONS

ZYPADHERA® olanzapine powder and solvent for prolonged release suspension for injection

FOR DEEP INTRAMUSCULAR GLUTEAL INJECTION ONLY.
DO NOT ADMINISTER INTRAVENOUSLY OR SUBCUTANEOUSLY

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 and safety needle (Hypodermic Device)
- One 19-gauge, 38 mm Hypodermic safety needle
- Two 19-gauge, 50 mm Hypodermic safety needles
- Patient Information Leaflet
- Reconstitution and Administration card (this leaflet)
- Hypodermic Device Safety Information and Instructions for Use leaflet

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.

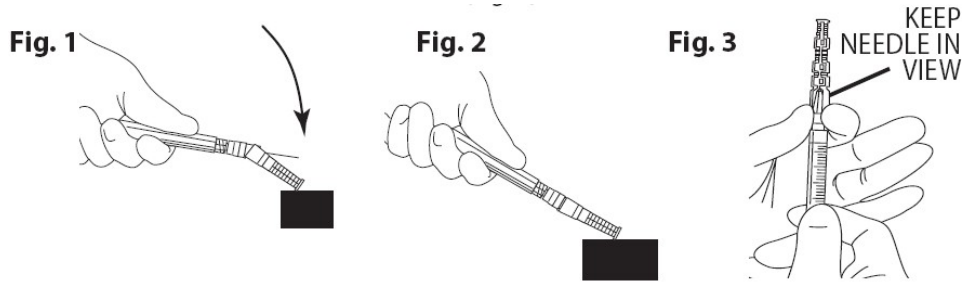
STEP 2: Determining solvent volume for reconstitution
This table provides the amount of solvent required to reconstitute ZYPADHERA powder for prolonged release suspension for injection.

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.

STEP 3: Reconstituting ZYPADHERA

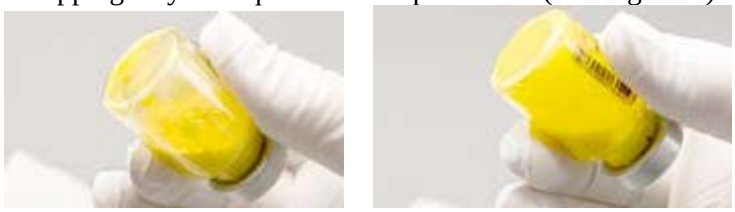
1. Loosen the powder by lightly tapping the vial.
2. Open the pre-packaged Hypodermic syringe and needle with needle protection device. Peel blister pouch and remove device. Attach a syringe (if not already attached) to the Luer connection of the device with an easy twisting motion. Seat the needle firmly on the device with a push and a clockwise twist, then pull the needle cap straight away from the needle. Failure to follow these instructions may result in a needle stick injury.
3. Withdraw the pre-determined solvent volume (Step 2) into the syringe.
4. Inject the solvent volume into the powder vial.
5. Withdraw air to equalize the pressure in the vial.
6. Remove the needle, holding the vial upright to prevent any loss of solvent.
7. Engage the needle safety device. 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 (Fig. 1), THE NEEDLE IS FIRMLY ENGAGED INTO THE SHEATH (Fig. 2).
8. Visually confirm that the needle is fully engaged into the needle protection sheath. Only remove the 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 (Fig. 3).



9. 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

10. 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.

11. 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. Reconstituted ZYPADHERA remains stable for up to 24 hours in the vial.

Administration

STEP 1: Injecting ZYPADHERA

This table confirms the final ZYPADHERA suspension volume to inject. Suspension concentration is 150 mg/ml olanzapine.

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

1. Determine which needle will be used to administer the injection to the patient. For obese patients, the 50 mm needle is recommended for injection:
   - If the 50 mm needle is to be used for injection, attach the 38 mm safety needle to the syringe to withdraw the required suspension volume.
   - If the 38 mm needle is to be used for the injection, attach the 50 mm safety needle to withdraw the required suspension volume.
2. Slowly withdraw the desired amount. Some excess product will remain in the vial.
3. Engage the needle safety device and remove needle from syringe.
4. 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.
5. Select and prepare a site for injection in the gluteal area. DO NOT INJECT INTRAVENOUSLY OR SUBCUTANEOUSLY.
6. 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.
7. Engage the needle safety device. (Fig. 1 and 2)
8. 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.