Instructions to Reconstitute and Administer ZYPREXA RELPREVV

ZYPREXA® Relprevv™
(olanzapine) For Extended Release Injectable Suspension

! FOR DEEP INTRAMUSCULAR GLUTEAL INJECTION ONLY.
NOT TO BE INJECTED INTRAVENOUSLY OR SUBCUTANEOUSLY.

For Important Safety Information, including boxed warnings, see the full Prescribing Information provided.

STEP 1 PREPARING MATERIALS

Figure 1: *Contents of convenience kit.*

Convenience kit includes:
(See Figure 1 on left)

- Single-dose vial of ZYPREXA RELPREVV powder
- 3-mL vial of diluent
- One 3-mL syringe with pre-attached 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro® needle with needle protection device
- Two 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needles with needle protection device.
  - – For obese patients, a 2-inch (50 mm), 19-gauge or larger needle (not included in convenience kit) may be used for administration.

! *ZYPREXA RELPREVV must be suspended using only the diluent supplied in the convenience kit.*

It is recommended that gloves are used when reconstituting, as ZYPREXA RELPREVV may be irritating to the skin. Flush with water if contact is made with skin.

STEP 2 DETERMINING RECONSTITUTION VOLUME

Dose	Vial Strength	Diluent to Add
150 mg	210 mg	1.3 mL
210 mg	210 mg	1.3 mL
300 mg	300 mg	1.8 mL
405 mg	405 mg	2.3 mL

Refer to the table at left to determine the amount of diluent to be added to powder for reconstitution of each vial strength.

! *It is important to note that there is more diluent in the vial than is needed to reconstitute.*

STEP 3 RECONSTITUTING ZYPREXA RELPREVV

Figure 2: *Tap firmly to mix.*

Figure 3: *Check for unsuspended powder and repeat tapping if needed.*

Figure 4: *Vigorously shake vial.*

3.1 Loosen the powder by lightly tapping the vial.

3.2 Open the prepackaged Hypodermic Needle-Pro syringe and needle with needle protection device.

3.3 Withdraw the pre-determined diluent volume (Step 2) into the syringe.

3.4 Inject the diluent into the powder vial.

3.5 Withdraw air to equalize the pressure in the vial by pulling back slightly on the plunger in the syringe.

3.6 Remove the needle from the vial, holding the vial upright to prevent any loss of material.

3.7 Engage the needle safety device (refer to complete Hypodermic Needle-Pro instruction for use).

3.8 Pad a hard surface to cushion impact *(see Figure 2)*. Tap the vial firmly and repeatedly on the surface until no powder is visible.

3.9 Visually check the vial for clumps. Unsuspended powder appears as yellow, dry clumps clinging to the vial. Additional tapping may be required if large clumps remain *(see Figure 3)*.

3.10 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 4)*.

If foam forms, let the vial stand to allow foam to dissipate.

If the product is not used right away, it should be shaken vigorously to re-suspend. Reconstituted ZYPREXA RELPREVV remains stable for up to 24 hours in the vial.

STEP 4 INJECTING ZYPREXA RELPREVV

Dose	Final Volume to Inject
150 mg	1 mL
210 mg	1.4 mL
300 mg	2 mL
405 mg	2.7 mL

Refer to the table above to determine the final volume to inject. **Suspension concentration is 150 mg/mL ZYPREXA RELPREVV.**

! *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.

4.1 Attach a new safety needle to the syringe.

4.2 Slowly withdraw the desired amount into the syringe.

! *SOME EXCESS PRODUCT WILL REMAIN IN THE VIAL.*

4.3 Engage the needle safety device and remove needle from syringe.

4.4 For administration, select the 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needle with needle protection device. For obese patients, a 2-inch (50 mm), 19-gauge or larger needle (not included in convenience kit) may be used. **To help prevent clogging, a 19-gauge or larger needle must be used.**

4.5 Attach the new safety needle to the syringe prior to injection. Once the suspension has been removed from the vial, it should be injected immediately.

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4.6 Select and prepare a site for injection in the **gluteal** area.

4.7 After insertion of the needle into the muscle, ! *aspirate for several seconds to ensure that no blood appears.* If any blood is drawn into the syringe, discard the syringe and the dose and begin with a new convenience kit. The injection should be performed with steady, continuous pressure.

! *DO NOT MASSAGE THE INJECTION SITE.*

4.8 Engage the needle safety device.

4.9 Dispose of the vials, needles, and syringe appropriately after injection. The vial is for single-dose only.

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JELCO® HYPODERMIC NEEDLE-PRO® NEEDLE with NEEDLE PROTECTION DEVICE

1. DESCRIPTION:

The Jelco Hypodermic Needle-Pro device is a sterile, single-dose device. It includes a needle and needle safety sheath. The Needle-Pro device can be used with a Luer slip or Luer lock syringe.

2. INDICATIONS FOR USE:

This device is intended for injection or aspiration of fluids. The needle protection device covers the needle after use to help prevent needle sticks.

3. CONTRAINDICATIONS:

None known.

4. WARNINGS:

4.1 A needle stick with a contaminated needle may cause infectious diseases.

4.2 Intentional disengagement of the Needle-Pro device may result in a needle stick with a contaminated needle.

4.3 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 Needle-Pro device. The Needle-Pro 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.

4.4 Mishandling of the needle protection device may cause needles, especially short or small gauge needles, to bend whereby they protrude from the needle protection sheath, which may result in a contaminated needle-stick.

4.5 Do not use with Paraldehyde.

5. CAUTION:

5.1 Do Not Reuse: Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single-dose only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

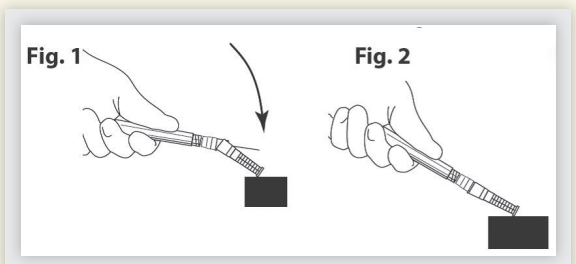
5.2 Follow standard infection control procedures as specified by the Centers for Disease Control and Prevention (USA) or local equivalent.

6. INSTRUCTIONS FOR USE:

6.1 Peel blister pouch and remove device.

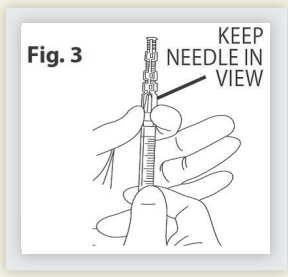
6.2 Attach a syringe (if not already attached) to the Luer connection of the Needle-Pro device with an easy twisting motion. Seat the needle firmly on the Needle-Pro device with a push and a clockwise twist, then pull the needle cap straight away from the needle.

6.3 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 (Fig. 1), The Needle Is Firmly Engaged Into The Sheath (Fig. 2).



6.4 Visually confirm that the needle is fully engaged into the needle protection sheath.

6.5 Only remove the Needle-Pro device with 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).



6.6 After use, place sharps in a suitable sharps container. Dispose of contaminated product in a safe manner according to Centers for Disease Control and Prevention, USA and Federal/State/Local regulations (EPA, OSHA) and health care facility guidelines or local equivalent.

NOTE: Additional dead space added by Needle-Pro device averages 0.036mL.

! **Caution** • Do Not Reuse • Not made with natural rubber latex • Do not use if package is damaged • Sterilized using ethylene oxide • Non-pyrogenic fluid path • **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician • Catalogue Number • Batch Code • Date of Manufacture • Use by • Quantity

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Literature revised: August 25, 2014

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