

Instructions for Use

ZILRETTA®

(triamcinolone acetonide extended-release injectable suspension)

For intra-articular injection only

Single-dose device

Do not reuse.

IMPORTANT INFORMATION

- ZILRETTA must be prepared using only the diluent supplied in the kit.
- To ensure proper dosing, it is important that you follow the preparation and administration steps outlined in these instructions.
- Promptly inject ZILRETTA after preparation to avoid settling of the suspension.
- ZILRETTA is supplied as a single-dose kit and administered as a suspension containing microspheres.
- The ZILRETTA powder vial contains an overfill to allow the appropriate dose to be withdrawn. ZILRETTA is a suspension product and it is normal for some residue to be left behind on the vial walls after withdrawing the contents.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.
- Use proper aseptic technique throughout the dose preparation and administration procedure.
- Inspect all kit components to confirm they have not expired and the seals are intact.
- For additional information, visit www.zilretta.com or call Flexion Therapeutics at 1-844-FLEXION (353-9466).

MATERIALS REQUIRED (Fig. 1)

Supplied

- One 32 mg vial of ZILRETTA microsphere powder
- One 5 mL vial of sterile diluent
- One sterile vial adapter

Not Supplied

- Three sterile needles, 21-gauge, 1½" length
- One sterile Luer Lock compatible syringe, 5 mL
- Sterile alcohol pads
- Paper towels or pad to cushion vial tapping (not shown in Fig. 1)
- Medical-grade gloves (not shown in Fig. 1)



Figure 1

1. Vial Preparation

Loosen Powder.

Place two paper towels or a pad on a properly-cleaned hard surface.

Grip the top of the ZILRETTA powder vial and tap firmly and repeatedly on the padded surface. Tap the vial until excess powder is dislodged from the vial and stopper (Fig. 2). Before continuing, ensure that powder moves freely within the vial.

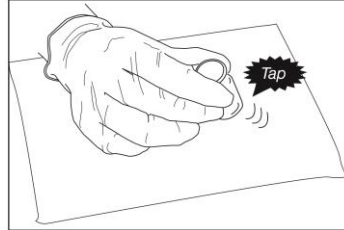


Figure 2

Inspect ZILRETTA Powder Vial.

As shown in Figure 3, the vial on the left, with the X, requires additional tapping because the powder is not properly dislodged. The vial on the right shows the powder properly dislodged and ready for the next step.

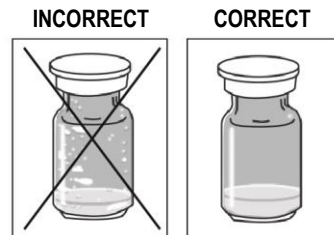


Figure 3

Remove Caps.

Remove the flip-off caps from the ZILRETTA powder and diluent vials (Fig. 4).

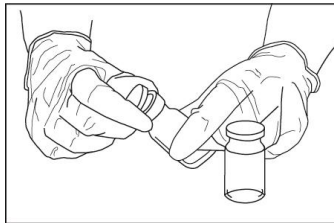


Figure 4

Clean Vials.

Clean the ZILRETTA powder and diluent vial tops with an alcohol pad.

Use a separate alcohol pad for each vial.

Peel Off Vial Adapter Cover.

Peel off the paper cover from the vial adapter package (Fig. 5).

Leave the adapter in the plastic holder.

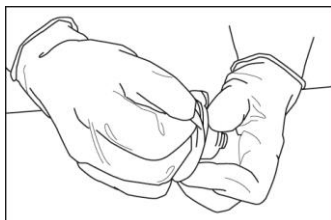


Figure 5

Attach Vial Adapter to ZILRETTA Powder Vial.

Grip the plastic holder that contains the vial adapter.

As shown in Figure 6, place the ZILRETTA powder vial on a flat surface. In a vertical orientation, gently push the adapter down onto the ZILRETTA powder vial until the spike on the adapter penetrates the rubber stopper on the ZILRETTA powder vial. The adapter will snap into place.

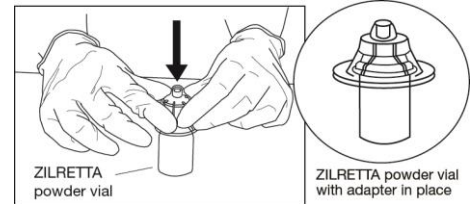


Figure 6

2. Diluent Preparation

Attach Needle.

Attach a needle to the syringe and remove the needle guard.

Withdraw Diluent.

With a syringe and needle, withdraw 5 mL of diluent.

Replace the needle guard.

3. Dose Preparation

Remove Holder.

Remove the plastic holder from the vial adapter (Fig. 7).

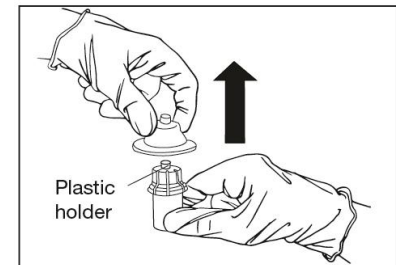


Figure 7

Remove Needle.

Remove the needle from the syringe containing diluent.

Attach Diluent Syringe.

Attach the syringe onto the vial adapter by pushing down and turning clockwise until you feel resistance (Fig. 8).

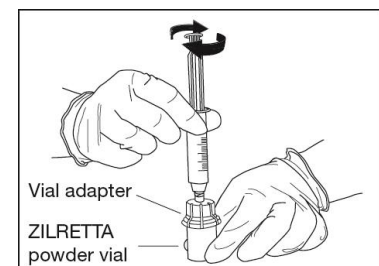


Figure 8

Continued on other side

Transfer Diluent.

Slowly and completely push down the syringe plunger to transfer the diluent into the ZILRETТА powder vial (Fig. 9).

Note: Equalize the pressure in the syringe by slowly pulling back the plunger to the 5 mL mark. Ensure that no solution is drawn back into the syringe at this stage.

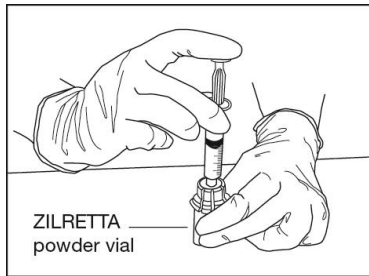


Figure 9

Mix Diluent and Powder (Fig. 10).

With the syringe still attached to the ZILRETТА powder vial, hold the syringe and vial at a slight angle. Tap the bottom edge of the vial firmly and repeatedly, in a circular motion, on the padded surface.

Swirl gently every five or six taps.

Tap for at least one minute until all powder is completely dispersed.

Note: Avoid vigorous shaking of the vial to minimize foaming.

Note: At least one minute of tapping and gentle swirling is required to achieve uniform suspension.

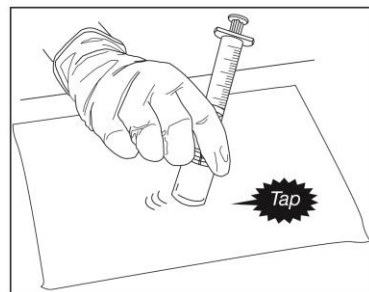


Figure 10

Inspect Vial.

Inspect the ZILRETТА powder vial to ensure no clumped powder is visible and a uniform suspension has been achieved. A properly mixed suspension will be milky white, contain no clumps, and move freely down the vial wall.

As shown in Figure 11, the vial on the left, with the X, requires more tapping and gentle swirling because the powder is not mixed properly with the diluent. The vial on the right shows the powder properly mixed and ready for the next step.

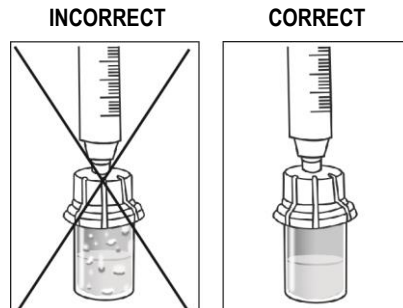


Figure 11

Note: If needed, the ZILRETТА suspension can be stored in the vial for up to 4 hours at ambient conditions. The syringe must remain on the vial adapter while the suspension remains in the vial.

Withdraw Contents into Syringe.

Swirl the vial gently for at least 10 seconds to ensure the powder is fully suspended. Immediately depress the plunger fully and then invert the syringe so the vial is directly on top of the syringe (Fig. 12).

Hold the syringe in a completely vertical position, per the illustration on the right, in Figure 12.

Withdraw the full contents from the ZILRETТА vial into the syringe.

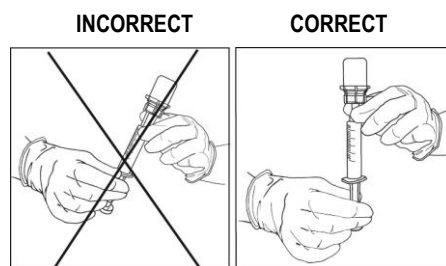


Figure 12

Note: ZILRETТА is a suspension product and it is normal for some residue to be left behind on the vial walls after withdrawing the contents.

Remove Syringe.

Remove the syringe from the vial adapter by turning counter-clockwise.

Remove Air Bubbles.

Attach a new needle to the syringe and remove the needle guard.

Inspect for bubbles with the syringe held in a completely vertical position (needle upward). If bubbles are observed, gently tap the syringe with your finger until the bubbles rise to the top. Eliminate all bubbles by slowly depressing the plunger to displace the air from the syringe.

Replace the needle guard.

Attach New Needle.

Remove and discard the needle.

Attach a new needle.

4. Administration

Invert Syringe.

To ensure the powder is suspended, gently invert the syringe containing ZILRETТА several times just prior to administration, as shown in Figure 13.

Grip the syringe firmly and turn it so the syringe plunger is pointing straight down. Then turn the syringe gently, 180 degrees, until the plunger is pointing straight up.

Invert the syringe several times to ensure a properly mixed suspension.

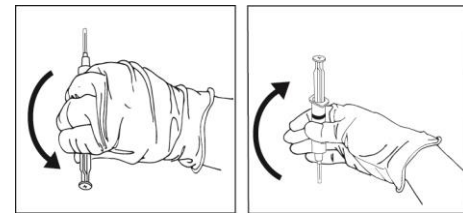


Figure 13

A properly mixed suspension will be uniformly milky white and contain no clumps.

Inspect Syringe.

As shown in Figure 14, the syringe on the left, with the X, requires more inversions (turning) to properly mix the suspension. The syringe on the right shows the suspension properly mixed and ready for the next step.

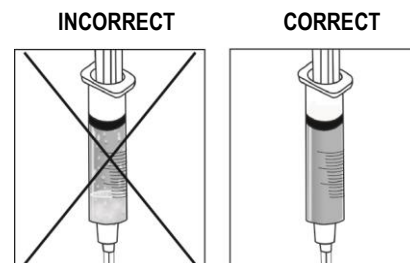


Figure 14

Administer ZILRETТА.

The usual technique for intra-articular injection should be followed.

Aspiration of synovial fluid may be performed based on clinical judgment prior to administration of ZILRETТА.

Do not reuse excess ZILRETТА. Any excess suspension in the vial should be thrown away immediately after the injection. Leftover ZILRETТА in the vial must never be reused for another injection.

Note: The entire contents of the syringe must be injected to ensure the intended dose of ZILRETТА is delivered.

Note: Discard all used components in an appropriate medical waste container according to local regulations.

Note: ZILRETТА is for intra-articular use only. ZILRETТА is not intended for epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous use.

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