



400 mg bupivacaine and 12 mg meloxicam
Each mL contains 23.25 mg bupivacaine and 0.88 mg meloxicam

Intended Use

ZYNRELEF is indicated in adults to produce postsurgical analgesia for up to 72 hours after soft tissue, foot and ankle, and other orthopedic procedures in which direct exposure to articular cartilage is avoided.

Limitations of Use

Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large 4 or more level spinal, and head and neck procedures.

Instructions For Use

Dose Information

A single-dose application of a viscous solution administered directly via a needle-free syringe to coat the affected tissue within the surgical site prior to suturing. Two syringes are provided to aid in application.

Preparing the Product

Withdraw the amount needed up to 14 mL. This product does not require mixing. During preparation, do not mix with water, saline or other local anesthetics. Preparation is typically done in the Operating Room. Follow your facility's standard operating procedures regarding aseptic and sterile preparation and disposal of unused contents in the vial.

Storing the Product

ZYNRELEF kit should be stored at 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature], protected from light and moisture.

For Operating Room Preparation

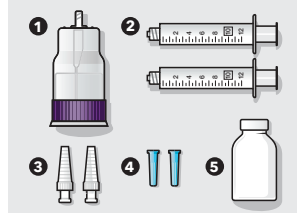
It is recommended that a 2-person team prepare this product: one sterile person and one non-sterile person. If product is prepared in advance of surgery, blue syringe tip caps 4 may be used to cap the syringe until ready for application. Before administration, remove the blue syringe tip cap and attach the Luer lock applicator 5.

The ZYNRELEF Kit Contents

Use only the components listed below supplied for use with ZYNRELEF.

- 1 20 mL Vial Access Needle (VAN) (Part #12027-325-31) (sterile)
- 2 12 mL Luer Lock Syringe (Part #4100-X00V0) (sterile) (2x)
- 3 Luer Lock Applicator (Part #709689) (sterile) (2x)
- 4 Blue Tip Caps (Part #305819) (sterile) (2x) (preparation in advance)
- 5 14 mL ZYNRELEF Vial (contents sterile, exterior not sterile)

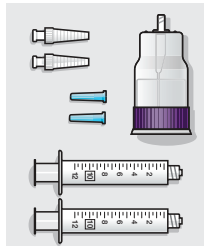
Turn over for Administration Information



⚠ Do not substitute any of the components.

Preparation

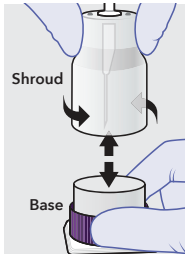
1 Prepare Components



NON-STERILE

- A) Check packaging for damage or tears.
 - B) Open all components onto the sterile field.
- ⚠ Do not substitute any of the components.

2 Prepare Vial Access Needle



STERILE

- A) In the sterile field, separate the Vial Access Needle (VAN) into two pieces – base and shroud.
- B) If the two pieces are locked together, twist and pull apart at the same time.

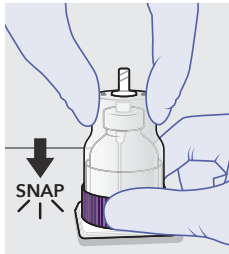
3 Prepare Vial



NON-STERILE

- A) Flip cap off of vial.
 - B) Cleanse septum with alcohol wipe.
 - C) Place non-sterile vial into base of sterile VAN.
- ⚠ Do not remove the stopper or attempt to pour the vial contents.
- ⚠ Do not touch base of VAN.

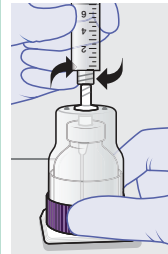
4 Attach Vial Access Needle Shroud



STERILE

- A) Position shroud above vial.
 - B) Insert needle into the septum of the vial.
 - C) Push down firmly on the shroud until the shroud "snaps" into the base and the needle is fully inserted.
- ⚠ Ensure shroud is fully connected to the base to avoid compromising sterility.

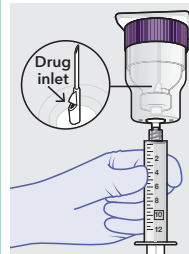
5 Attach Syringe



STERILE

- A) Attach the provided syringe to the top (Luer) of the VAN shroud.
- Note: Air does not need to be pushed into the vial.

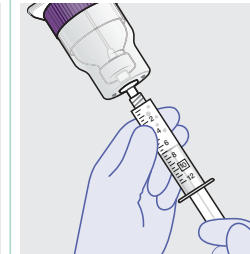
6 Invert Syringe



STERILE

- A) Invert syringe and VAN as pictured above.
 - B) Wait until the drug product fills the neck of the vial to cover drug inlet.
- Note: Drug inlet is at the base of the needle, not at the tip.

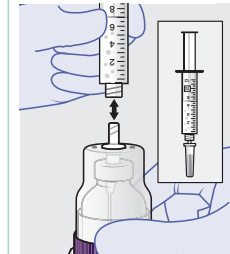
7 Withdraw Product



STERILE

- A) Using a continuous motion, slowly withdraw the desired amount of ZYNRELEF from the vial.
- Note: It is normal for there to be air bubbles in the syringe.
- Note: Product is very thick. It may take approximately 30 seconds to withdraw per syringe.
- Note: Pushing or pumping the plunger rod up and down at any point may prolong the withdrawal process.

8 Attach Luer Lock Applicator



STERILE

- A) Remove syringe from VAN and attach Luer lock applicator.
- If product is prepared in advance of surgery, attach only the blue tip cap to the syringe until ready for application.
- Before administration, remove the blue tip cap and attach the Luer lock applicator.
- B) Place syringe on sterile surface.
- Note: Vial contains overflow to account for amount that remains in the components.

Frequently Asked Questions

Can I attempt to do the entire preparation process on my own? A non-sterile person is needed to place the non-sterile vial in the VAN; all other steps are to be performed by the sterile person.

Is there any way to speed up the withdrawal time? The withdrawal time is faster when the vial is at the upper end of the recommended storage condition (25 °C or 77 °F).

Do I need to dilute this product to expand the volume? No. The product should not be diluted.

Can I pour this product in a sterile cup? No, you will be unable to pull an effective dose from the sterile cup due to the thick nature of the product.

What should I do if I drop a syringe or any of the other components? If you compromise sterility of any sterile component of the ZYNRELEF kit, use a new kit or contact HERON CONNECT at 1-844-437-6611 for a replacement.



Turn over for
Preparation Information



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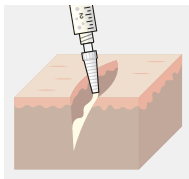
Administration Information

Please familiarize yourself with this information before you use this product for the first time.

ZYNRELEF should only be administered with the syringe and Luer lock applicator provided in the ZYNRELEF kit.

Administration

- ADMINISTER ZYNRELEF VIA INSTILLATION ONLY.
- ZYNRELEF should not be administered via the following routes:
 - Epidural
 - Intrathecal
 - Intravascular
 - Intra-articular
 - Regional nerve blocks
 - Pre-incisional or pre-procedural locoregional anesthetic techniques
- ZYNRELEF is applied without a needle into the surgical site following final irrigation and suction and prior to suturing.
 - ⚠ Only apply ZYNRELEF after final irrigation and suction of each layer before closing, if multiple tissue layers are involved.
- Using the Luer lock applicator attached to the syringe, apply ZYNRELEF to the tissues within the surgical site that could result in pain generation.
- Use a sufficient amount to coat the tissues. For small spaces, ensure there is not an excess that could be expressed from the site during closure.
- Only apply ZYNRELEF to the tissue layers below the skin incision and not directly onto the skin.



- ZYNRELEF does not degrade sutures.

⚠ When tying knots with monofilament sutures, contact with ZYNRELEF may cause knots to loosen or untie due to the viscosity of ZYNRELEF. In vitro studies showed an increase in elasticity with monofilament sutures exposed to ZYNRELEF with unknown clinical significance. Minimize administration of ZYNRELEF near the incision line and wipe off excess ZYNRELEF from the skin prior to suturing. Three or more knots ending in a multi-throw knot (e.g. a Surgeon's knot) are recommended with monofilament sutures. Braided or barbed sutures are recommended, especially for closure of deeper layers.

Important Information

- The amount of ZYNRELEF required depends upon the surgical area of tissue to be treated.
- ZYNRELEF spreads easily and covers a large area.
- Diluting ZYNRELEF is not needed for efficacy.
 - ⚠ ZYNRELEF cannot be mixed with water, saline, or other local anesthetics as the product will become very viscous and difficult to administer.
- When ZYNRELEF comes in contact with moisture in the tissues, it becomes more viscous, allowing it to stay in place.
- Avoid additional use of local anesthetics within 96 hours following administration of ZYNRELEF.
 - ⚠ Overall local anesthetic exposure must be considered.

