

### 400 mg bupivacaine and 12 mg meloxicam Each mL contains 29.25 mg bupivacaine and 0.88 mg meloxicam

#### Intended Use

**Preparation** 

ZYNRELEF is indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical 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**

Only withdraw 7 mL of ZYNRELEF into each syringe. 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, syringe tip caps 4 may be used to cap the syringe until ready for application. Before administration, remove the syringe tip cap and attach the Luer lock applicator 3.

### The ZYNRELEF Kit Contents

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

- **1** Vented Vial Spike (Part #011-CS-75) (sterile)
- 2 12 mL Luer Lock Syringe (Part #4100-X00V0) (sterile) (2x)
- 3 Luer Lock Applicator (Part #709689) (sterile) (2x)
- **4** Tip Caps (Part #305819) (sterile) (2x) (preparation in advance)
- 5 14 mL ZYNRELEF Vial (contents sterile, exterior not sterile)



### **Frequently Asked Questions**

Can I attempt to do the entire preparation process on my own? It is recommended that this be done as a 2-person team to maintain sterility.

Is there any way to speed up the withdrawal time? This medication is specially formulated to coat the affected area. You should not attempt to warm or dilute this product in any way.

What if I touch the aluminum collar when attaching the vented vial spike adapter? Replace your sterile gloves and continue with next steps

Do I have to wait until the vial is inverted to push in air? Proper insertion of air after inverting the vial improves withdrawal time. 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.

Turn over for Administration Information



(7) Withdraw Product



### STERILE

- A) Invert the vial using the syringe. B) Allow product to fill the neck of the vial.
- **C)** Push air into vial and wait for the air bubble to rise.
- D) Withdraw 7 mL of product. It is normal for there to be small air bubbles in the syringe.

Note: Product is very thick. It may take a few minutes to withdraw.

#### NON-STERILE

You may assist the sterile person with inverting the vial if necessary by holding the non-sterile vial.

(8) Repeat With **Second Syringe** 



#### STERILE

- A) Return vial to non-sterile surface.
- **B)** Remove syringe from vial and attach Luer lock applicator.
- **C)** Place syringe on sterile surface.
- **D)** Repeat steps 5–8 with second syringe.

#### NON-STERILE

Hold the vial in place for attachment of second syringe.

What should I do if I drop a syringe or any of the other components? Use replacement kit components that are individually supplied separate from the kit.





400 mg bupivacaine and 12 mg meloxicam Each mL contains 29.25 mg bupivacaine and 0.88 mg meloxicam

# **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

- **1.** ZYNRELEF is applied without a needle into the surgical site following final irrigation and suction and prior to suturing.
- A Only apply ZYNRELEF after final irrigation and suction of each layer before closing, if multiple tissue layers are involved.
- **2.** Using the Luer lock applicator attached to the syringe, apply ZYNRELEF to the tissues within the surgical site that could result in pain generation.
- **3.** 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.

**4.** Only apply ZYNRELEF to the tissue layers below the skin incision and not directly onto the skin.

- 5. ZYNRELEF does not degrade sutures.
- A When using monofilament sutures, use 3 or more knots as contact with ZYNRELEF may cause a single knot to loosen or untie.

## **Important Information**

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

