Important Safety Information

EXPAREL is contraindicated in obstetrical paracervical block anesthesia.

Adverse reactions reported with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported with an incidence greater than or equal to 10% following EXPAREL administration via interscalene brachial plexus nerve block were nausea, pyrexia, and constipation.

If EXPAREL and other non-bupivacaine local anesthetics, including lidocaine, are administered at the same site, there may be an immediate release of bupivacaine from EXPAREL. Therefore, EXPAREL may be administered to the same site 20 minutes after injecting lidocaine.

EXPAREL is not recommended to be used in the following patient population: patients <18 years old and/or pregnant patients.

Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease.

Warnings and Precautions Specific to EXPAREL

Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL.

EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks other than interscalene brachial plexus nerve block, or intravascular or intra-articular use.

The potential sensory and/or motor loss with EXPAREL is temporary and varies in degree and duration depending on the site of injection and dosage administered and may last for up to 5 days, as seen in clinical trials.

Warnings and Precautions for Bupivacaine-Containing Products

Central Nervous System (CNS) Reactions: There have been reports of adverse neurologic reactions with the use of local anesthetics. These include persistent anesthesia and paresthesia. CNS reactions are characterized by excitation and/or depression.

Cardiovascular System Reactions: Toxic blood concentrations depress cardiac conductivity and excitability which may lead to dysrhythmias, sometimes leading to death.

Allergic Reactions: Allergic-type reactions (e.g., anaphylaxis and angioedema) are rare and may occur as a result of hypersensitivity to the local anesthetic or to other formulation ingredients.

Chondrolysis: There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics, which is an unapproved use.

Methemoglobinemia: Cases of methemoglobinemia have been reported with local anesthetic use.

Please refer to accompanying full Prescribing Information.

For more information, please visit www.EXPAREL.com or call 1-855-RX-EXPAREL (793-9727).

References:

Choose EXPAREL as part of a multimodal approach to reduce postsurgical pain and minimize the use of opioids.

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FAST FACTS

**Why use a single-dose, long-lasting, non-opioid option for postsurgical pain?**
- EXPAREL reduces or eliminates the need for opioids* while providing significant long-lasting pain control
- EXPAREL eliminates the need for pumps and catheters that could hinder patient recovery

*The clinical benefit of the decrease in opioid consumption was not demonstrated in the pivotal trials.

**How does EXPAREL work?**
EXPAREL uses DepoFoam®, an innovative drug delivery technology, to extend analgesia.²

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**Which surgeries are EXPAREL appropriate for?**
- Facial, plastic, and oral/maxillofacial, the 133 mg (10 mL) dose is appropriate
- Such as abdominal, colorectal, general, breast, gynecologic, orthopedic, and spine procedures.

**How should EXPAREL be administered?**
EXPAREL does not diffuse throughout tissues in the same manner as bupivacaine HCl. Administer EXPAREL differently than bupivacaine HCl. Utilizing a moving needle technique, EXPAREL should be injected slowly (generally 1-2 mL per injection) with frequent aspiration to check for blood and minimize the risk of inadvertent intravascular injection.

**Where and how should EXPAREL be expanded?**
EXPAREL contains liposomal bupivacaine. When EXPAREL is administered, bupivacaine is released over time as the liposomal particles reorganize and the lipid membranes reorganize.³

**Why and how should EXPAREL be expanded?**
To ensure optimal analgesic coverage, the volume should be expanded for larger surgical sites.

- The 266 mg (20 mL) vial of EXPAREL can be expanded with normal saline or lactated Ringer’s solution up to a total volume of 300 mL.
- To ensure early analgesic onset, bupivacaine HCl may be admixed with EXPAREL as part of the total expanded volume, as long as the ratio of the milligram dose of bupivacaine HCl to EXPAREL does not exceed 1:2.

**What is the dosing for EXPAREL?**
The recommended dose is 133 mg (10 mL) and is based on the following factors:
- Individual patient factors that may impact the safety of an amide local anesthetic
- For infiltration and field blocks in larger procedures, such as abdominal, colorectal, general, breast, gynecologic, orthopedic, and spine, the 266 mg (20 mL) dose is appropriate
- When infiltrating small surgical sites, such as hand/foot, facial, plastic, and oral/maxillofacial, the 133 mg (10 mL) dose can be used

**What is the clinical experience with EXPAREL?**
More than 4.5 million patients have received EXPAREL across a range of soft tissue (eg, abdominal, anorectal, breast, plastic surgery, reconstructive, and genitourinary), oral/maxillofacial, orthopedic, and spine procedures.⁴

**What are the compatibility considerations with EXPAREL?**
- EXPAREL should not be admixed with drugs other than bupivacaine prior to administration
- Wait 20 minutes after administering lidocaine or other non-bupivacaine-based local anesthetics before administering EXPAREL into the same surgical site
- Allow topical antiseptics to dry before administering EXPAREL into the same surgical site
- Do not dilute EXPAREL with water for injection or other hypotonic agents as it will result in disruption of the liposomal particles

**What are the storage and handling recommendations for EXPAREL?**
- The 133 mg (10 mL) and 266 mg (20 mL) doses of EXPAREL are available in cartons of 4 and 10 vials
- EXPAREL vials should be stored and refrigerated between 2°C to 8°C (36°F to 46°F)
- Sealed, intact (unopened) EXPAREL vials may be held at a controlled room temperature of 20°C to 25°C (68°F to 77°F) for up to 30 days. Vials should not be re-refrigerated
- EXPAREL should not be frozen or exposed to high temperatures (>40°C or 104°F) for an extended period
- Do not administer EXPAREL if it is suspected of having been frozen or exposed to high temperatures. Vials should be visually inspected before use. Do not use the vial if the stopper is bulging
- Open vials of EXPAREL should be used within 4 hours
- Invert vials of EXPAREL multiple times to resuspend the particles immediately prior to withdrawal from the vial
- If pouring EXPAREL into a basin prior to use, stir the suspension in the basin prior to drawing up into the syringe

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**Please see Important Safety Information on reverse and refer to accompanying full Prescribing Information.**