EXPAREL Dose in Interscalene Brachial Plexus Nerve Block

EXPAREL is indicated for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks.

DOSING AND ADMINISTRATION

Use 133 mg (10 mL) of EXPAREL for interscalene brachial plexus nerve block

- The recommended dose of EXPAREL for interscalene brachial plexus nerve block in adults is 133 mg (10 mL), and is based upon one study of patients undergoing either total shoulder arthroplasty or rotator cuff repair
- Do not exceed maximum dosage of 133 mg (10 mL) of EXPAREL
- Inject slowly (1-2 mL per injection) with frequent aspiration to check for blood and minimize risk of inadvertent intravascular injection
- Administer EXPAREL with a 25-gauge or larger bore needle

ADMIXING WITH BUPIVACAINE HCl

- Bupivacaine HCl can be administered immediately before or admixed in the same syringe with EXPAREL, as long as the ratio of the milligram dose of bupivacaine HCl to EXPAREL does not exceed 1:2
  - One 10 mL vial contains 133 mg of EXPAREL, which is equivalent to 150 mg bupivacaine HCl
  - 1:2 ratio allows 75 mg bupivacaine HCl to 133 mg EXPAREL

<table>
<thead>
<tr>
<th>Admixing bupivacaine HCl with 133 mg (10 mL) of EXPAREL</th>
<th>0.25% bupivacaine HCl</th>
<th>0.5% bupivacaine HCl</th>
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<td>Up to 30 mL</td>
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<td>Up to 15 mL</td>
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- Do not admix EXPAREL with any other agents prior to administration

Important Safety Information

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.

Please see additional Important Safety Information inside and refer to accompanying full Prescribing Information for complete Dosage and Administration information.
**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 (eg, 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 complete Dosage and Administration information.
EXPAREL Dose in Field Blocks

DOSING AND ADMINISTRATION

Use 266 mg (20 mL) of EXPAREL for field blocks, such as TAP and PEC blocks

- Appropriate dose and total volume to be determined based on
  - Size of surgical site
  - Volume required to cover area
  - Individual patient factors that may impact safety

VOLUME EXPANSION AND ADMIXING

- 266 mg (20 mL) of EXPAREL can be administered unexpanded or expanded with up to 280 mL (for a total volume of 300 mL) of normal (0.9%) saline or lactated Ringer’s solution in a ratio of 1:14 dilution by volume
- When admixing with bupivacaine, remember the following:
  - One 20 mL vial contains 266 mg of EXPAREL, which is equivalent to 300 mg bupivacaine HCl
  - Do not admix EXPAREL with any other agents prior to administration

<table>
<thead>
<tr>
<th>Admixing bupivacaine HCl with 266 mg (20 mL) of EXPAREL</th>
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<tbody>
<tr>
<td>Up to 60 mL</td>
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<td>Up to 30 mL</td>
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- Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL

PEC, pectoralis; TAP, transversus abdominis plane.

Important Safety Information

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.

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

Please see additional Important Safety Information inside and refer to accompanying full Prescribing Information for complete Dosage and Administration information.