

Key Dosing Considerations With EXPAREL

INTERSCALENE BRACHIAL PLEXUS NERVE BLOCK

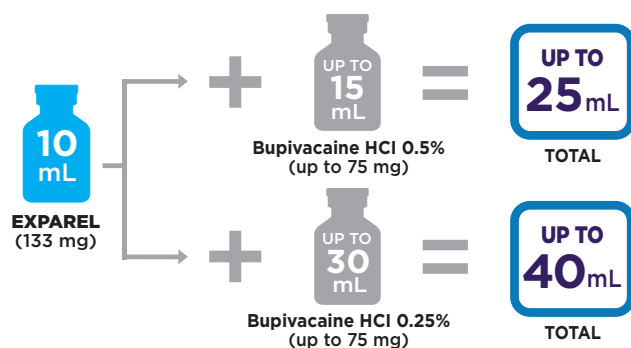


USE 133 mg (10 mL) OF EXPAREL FOR INTERSCALENE BRACHIAL PLEXUS NERVE BLOCK*

- Do not exceed maximum dosage of 133 mg (10 mL) of EXPAREL

ADMIXING WITH BUPIVACAINE HCl

- Bupivacaine HCl can be administered immediately before EXPAREL or admixed as part of the total expanded volume[†]
- Ensure ratio of milligram dose of bupivacaine HCl to EXPAREL does not exceed 1:2[†]
- One 10 mL vial contains 133 mg of EXPAREL, which is molar equivalent to 150 mg of bupivacaine HCl
 - 1:2 ratio allows 75 mg of bupivacaine HCl to 133 mg of EXPAREL



*The recommended dose is based on a study of patients undergoing either total shoulder arthroplasty or rotator cuff repair.
[†]Do not admix EXPAREL with any other agents prior to administration. Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL.

Indication

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.

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

FIELD BLOCK

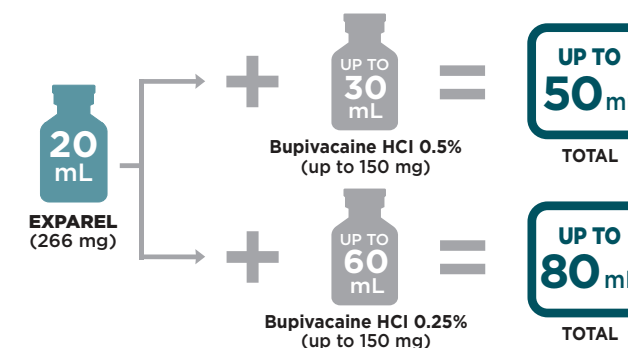


USE 266 mg (20 mL) OF EXPAREL FOR FIELD BLOCKS, SUCH AS TAP AND PEC BLOCKS[‡]

- Do not exceed maximum dosage of 266 mg (20 mL) of EXPAREL

VOLUME EXPANSION AND ADMIXING WITH BUPIVACAINE HCl

- 20 mL of EXPAREL can be expanded with up to 280 mL of normal saline or lactated Ringer's solution[§]
- Ensure ratio of milligram dose of bupivacaine HCl to EXPAREL does not exceed 1:2[†]
- One 20 mL vial contains 266 mg of EXPAREL, which is molar equivalent to 300 mg of bupivacaine HCl
 - 1:2 ratio allows 150 mg of bupivacaine HCl to 266 mg of EXPAREL



PEC, pectoralis nerve; TAP, transversus abdominis plane.

[†]Appropriate dose and total volume to be determined based on size of surgical site, volume required to cover area, and individual patient factors that may impact safety.

[§]Administer EXPAREL unexpanded or expanded to increase volume up to a final concentration of 0.89 mg/mL (ie, 1:14 dilution by volume).

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 full Prescribing Information.

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