EXPAREL®
(bupivacaine liposome injectable suspension)
OPIOID FREE

Administration Case Report With EXPAREL

This case report represents the individual experience of Dr David Leiman and is intended to demonstrate his methodology for using EXPAREL in a specific soft tissue surgery.

Pacira Pharmaceuticals, Inc. recognizes that there are alternative methodologies for administering local anesthetics, as well as individual patient considerations, when selecting the dose for a specific procedure.

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.

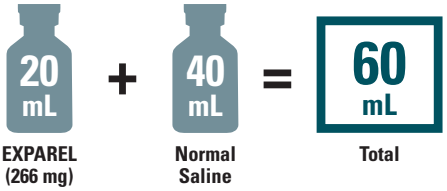
CASE INFORMATION

Physician Name	David Leiman, MD
Location	Houston, TX
Surgical Case Performed	Small bowel resection with primary anastomosis, ileostomy takedown, and removal of left subfascial port
Inpatient or Outpatient Procedure	Outpatient (23-hour observational stay)

PATIENT CHARACTERISTICS

Gender	Female
Age	53 years
Patient History and Characteristics	Patient has rectal cancer, a history of hemorrhoids and hypothyroidism, and 25 pack-years

PROCEDURAL DETAILS

Preoperative Analgesics Used	General anesthesia
Intraoperative Analgesics Used	Patient received the following IV medications: 2 mg midazolam, 100 mcg fentanyl, 40 mg lidocaine, 200 mg propofol, 50 mg rocuronium, 4 mg dexamethasone, 4 mg ondansetron HCl, 1 g APAP
Dose of EXPAREL and Total Volume Used	

APAP, paracetamol; IV, intravenous.

In this case report, Dr Leiman expanded the volume of EXPAREL with 40 mL of normal saline. In his current practice, Dr Leiman admixes 20 mL of EXPAREL with 40 mL of 0.25% bupivacaine HCl for a total volume of 60 mL.

The recommended dose of EXPAREL is based on the size of the surgical site, the volume required to cover the area, and individual patient factors that may impact the safety of an amide local anesthetic. The maximum dose of EXPAREL should not exceed 266 mg.

EXPAREL can be administered unexpanded (20 mL) or expanded to increase volume up to a total of 300 mL (final concentration of 0.89 mg/mL [ie, 1:14 dilution by volume]) with normal (0.9%) saline or lactated Ringer's solution.

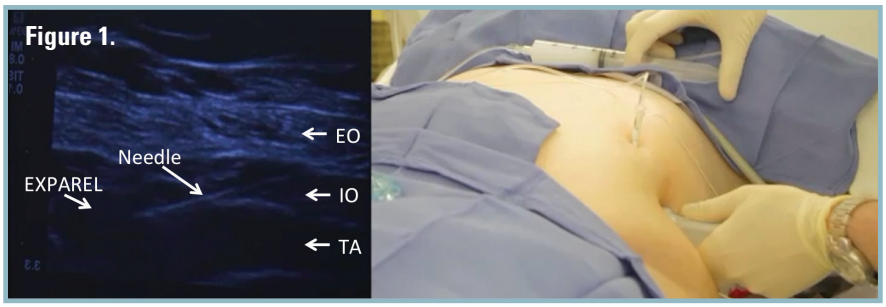
Bupivacaine HCl may be administered immediately before EXPAREL or admixed in the same syringe, as long as the ratio of the milligram dose of bupivacaine HCl to EXPAREL does not exceed 1:2. Admixing may impact the pharmacokinetic and/or physicochemical properties of EXPAREL, and this effect is concentration dependent. The toxic effects of these drugs are additive and their administration should be used with caution, including monitoring for neurological and cardiovascular effects related to local anesthetic systemic toxicity. Other than with bupivacaine, EXPAREL should not be admixed with other drugs prior to administration.

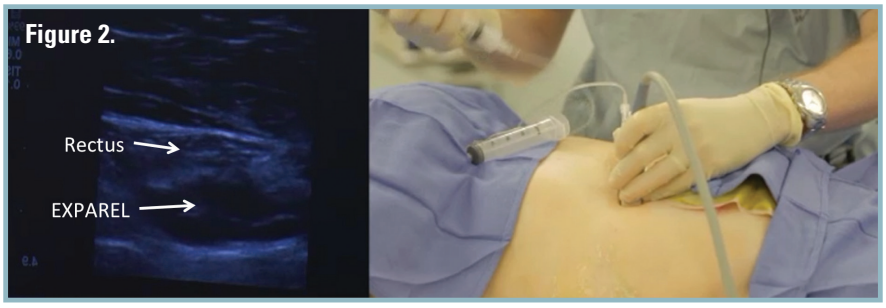
Please see Important Safety Information on reverse and refer to accompanying full Prescribing Information for complete Dosage and Administration information before using EXPAREL.

INFILTRATION NOTES

- Following induction but before surgery, ultrasound-guided TAP infiltrations were performed bilaterally using a 100-mm, 21-gauge blunt tip needle
  - 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) solution was infiltrated bilaterally for a total volume of 40 mL (see Figure 1)
- The remaining 20 mL of solution was infiltrated in two 10-mL aliquots on both sides of the supraumbilical portion of the rectus sheath (see Figure 2)

TAP, transversus abdominis plane.





EO, external oblique; IO, internal oblique; TA, transversus abdominis.

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.

Disclosure: Dr Leiman is a paid consultant for Pacira Pharmaceuticals, Inc.