

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 administration into the surgical site to produce postsurgical analgesia.

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 of age
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
Was the Volume of EXPAREL Expanded? If So, to What Volume?*	One 20 mL vial of EXPAREL (266 mg) expanded with 40 mL of preservative-free normal sterile saline for a total volume of 60 mL

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 undiluted (20 mL) or diluted 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.

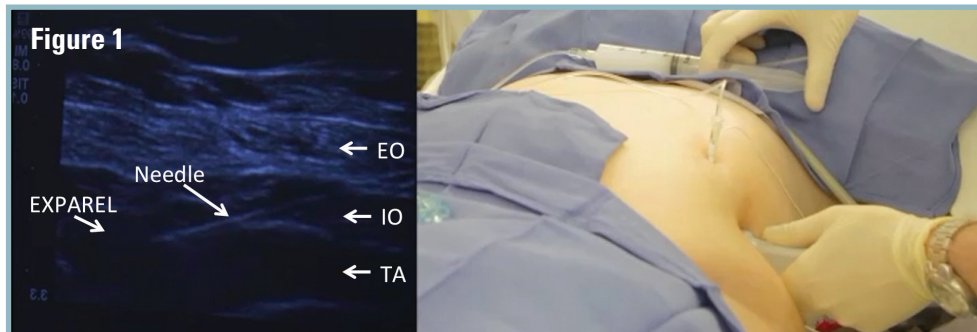
Bupivacaine HCl may be administered immediately before EXPAREL or admixed in the same syringe, as long as the ratio of the milligram dose of bupivacaine HCl to EXPAREL does not exceed 1:2. Admixing may impact the pharmacokinetic and/or physiochemical properties of EXPAREL, and this effect is concentration 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 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 the accompanying full Prescribing Information before using EXPAREL for complete Dosage and Administration information.

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 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. EXPAREL has not been studied for use in patients younger than 18 years of age.

Non-bupivacaine-based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more. Formulations of bupivacaine other than EXPAREL should not be administered within 96 hours following administration of EXPAREL.

Monitoring of cardiovascular and neurological status as well as vital signs should be performed during and after injection of EXPAREL as with other local anesthetic products.

Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations.

In clinical trials, the most common adverse reactions (incidence $\geq 10\%$) following EXPAREL administration were nausea, constipation, and vomiting.

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