

Administration Technique Guide

Capturing Clinician Experience With EXPAREL

This educational technique guide represents the individual experience of Dr. Rob Parrish and is intended to demonstrate his methodology for using EXPAREL in a specific orthopedic procedure.* Pacira Pharmaceuticals recognizes that there are alternative methodologies for administering local anesthetics, as well as individual patient considerations, when selecting the dose for a specific procedure.

CASE INFORMATION

Physician Name	Rob Parrish, MD, PhD
Affiliation	The Methodist Hospital; Houston, TX
Surgical Case Performed	Lumbar laminectomy and discectomy right L4-L5
Inpatient or Outpatient Procedure	Outpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	48 years of age
Patient History and Characteristics	Patient presented with back and right leg pain with L5 weakness. An MRI showed a large right L4-5 disc herniation with L5 root compression. Patient failed steroid therapy and had marked weakness in an L5 distribution.

PROCEDURAL DETAILS

Incision Size	1-in microdisc incision
Preoperative Analgesics Used	None
Intraoperative Analgesics Used	Fentanyl 100 mcg, IV acetaminophen 1000 mg
Was EXPAREL Diluted? If so, to What Volume	One 20 mL vial (266 mg) of EXPAREL was used (undiluted)

*The approval of EXPAREL was based on two pivotal clinical trials, excisional hemorrhoidectomy and bunionectomy, that demonstrated the safety and efficacy of the product. In the excisional hemorrhoidectomy trial, 266 mg of EXPAREL (one 20-mL vial) was diluted with 10 mL of preservative-free normal sterile saline. In the bunionectomy trial, an undiluted dose of 106 mg (8 mL) was used.

In the excisional hemorrhoidectomy trial, EXPAREL demonstrated postsurgical pain control with reduced opioid requirements for up to 72 hours. The median time to first opioid rescue was 14.3 hours for EXPAREL vs 1.2 hours for placebo. 28% of patients treated with EXPAREL received no postsurgical opioid rescue through 72 hours vs 10% of placebo-treated patients. The clinical benefit of the attendant decrease in opioid consumption was not demonstrated.

It is up to the individual prescriber to determine the relevance of the demonstration of efficacy and safety in these surgical models to their own surgical setting. The recommended dose of EXPAREL is based on the surgical site and the volume required to cover the area. The maximum dosage of EXPAREL should not exceed 266 mg.

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 TECHNIQUE

- 2 mL EXPAREL preemptively infiltrated bilaterally before microdisc incision was made for a total volume of 4 mL
- Remaining 16 mL of EXPAREL divided; 1 mL pooled on the lumbar-dorsal fascia; 4 mL injected into the muscles in several aliquots; the remaining EXPAREL infiltrated into the subcutaneous tissues above and below fascia prior to closure of that fascial layer (Figure 1)



FOLLOW-UP NOTES

Additional Postsurgical Medications Used/Prescribed

50 mcg of fentanyl and 0.6 mg of hydromorphone given in the PACU; patient pain score on arrival was 4 out of 10, patient reported pain scores of 3 out of 10 for the remainder of the postoperative period

Other Observations

The following medications were given for at-home care: oral acetaminophen/hydrocodone 5 mg/325 mg every 4-6 hours as needed for pain control; oral carisoprodol 350 mg every 8 hours as needed to control spasms

EXPAREL is a liposomal formulation of bupivacaine indicated for single-dose administration into the surgical site to produce postsurgical analgesia.

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. Other formulations of bupivacaine 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.

Disclosures: Dr. Parrish is a paid consultant of Pacira Pharmaceuticals, Inc.