EXPAREL®
(bupivacaine liposome injectable suspension)
OPIOID FREE

Administration Case Report With EXPAREL

This case report represents the individual experience of Dr William Tally and is intended to demonstrate his methodology for using EXPAREL in a specific orthopedic 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.

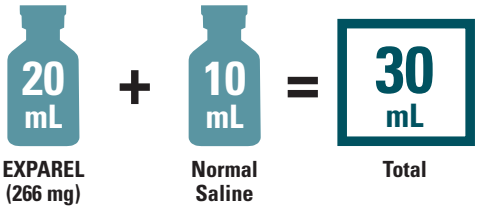
CASE INFORMATION

Physician Name	William Tally, MD
Affiliations	Assistant Professor of Orthopedic Surgery, Spine Specialist Georgia Regents University/Georgia School of Medicine Athens Orthopedic Clinic
Surgical Case Performed	L5—S1 MIS TLIF
Inpatient or Outpatient Procedure	Ambulatory surgery center

PATIENT CHARACTERISTICS

Gender	Male
Age	35 years of age
Patient History and Characteristics	Height: 5'7"; Weight: 175 lb
Pathology	Spondylolysis with grade 2 spondylolisthesis

PROCEDURAL DETAILS

Incision Size	Right side: 4.5 cm—Wiltse approach Left side: 1.25 cm—Wiltse stab incision for percutaneous screw insertion
Preoperative Analgesics Used	PO Oxycodone 10 mg, IV dexamethasone 10 mg
Intraoperative Analgesics Used	Bupivacaine HCl (0.25%) 10 mL
Dose of EXPAREL and Total Volume Used	

IV, intravenous; MIS TLIF, minimally invasive transforaminal lumbar interbody fusion; PO, by mouth.

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 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 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 the accompanying full Prescribing Information before using EXPAREL for complete Dosage and Administration information.

INFILTRATION NOTES

- After marking the incision site, EXPAREL® (bupivacaine liposome injectable suspension) was administered in the beginning of the case to be sure to avoid the epidural space
- An 18-gauge needle was placed transcutaneously along each screw pathway and confirmed with good position radiographically. EXPAREL was then injected along the entire pathway as each needle was removed (see Figures 1 and 2)
- 5 mL of EXPAREL mixture was used per screw
- 10 mL of EXPAREL mixture was used in the same plane for the Wiltse approach. EXPAREL was administered around the incision site, leaving 1-2 mL in each injection (see Figures 3 and 4)
- Caution was taken to not go into the foramen and transverse process

If any EXPAREL was seen in the incision site or near the dura, it was irrigated out during the procedure.

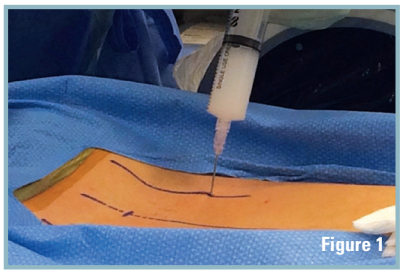


Figure 1

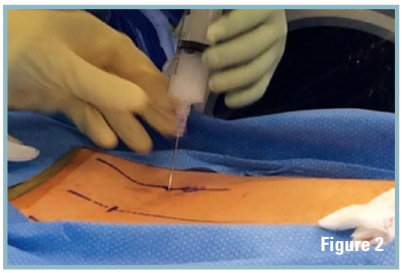


Figure 2

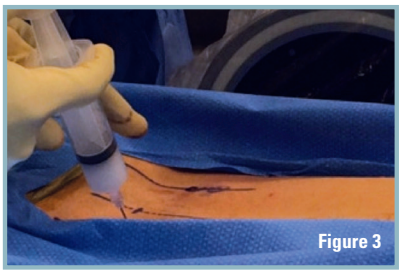


Figure 3

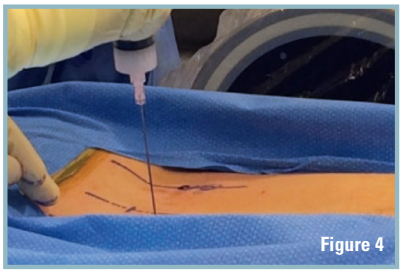


Figure 4

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.

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

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