

Administration Case Report With EXPAREL

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

Pacira BioSciences, 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.

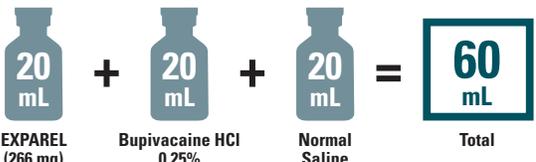
CASE INFORMATION

Physician Name	William J. Long, MD, FRCSC
Affiliation	Insall Scott Kelly® Institute for Orthopaedics & Sports Medicine
Surgical Case Performed	Right Total Hip Arthroplasty, Posterior Approach
Inpatient or Outpatient Procedure	Inpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	75 years of age
Patient History and Characteristics	Progressive right hip degenerative joint disease

PROCEDURAL DETAILS

Incision Size	8 cm mini posterior incision
Preoperative Analgesics Used	PO Gabapentin, PO oxycodone, PO celecoxib
Intraoperative Analgesics Used	Spinal anesthetic—1.1 mL 0.75% bupivacaine HCl, propofol PRN, dexamethasone 10 mg IV
Dose of EXPAREL and Total Volume Used	 <p>The diagram illustrates the combination of three 20 mL vials: EXPAREL (266 mg), Bupivacaine HCl 0.25%, and Normal Saline. These are summed to equal a total volume of 60 mL, which is highlighted in a box.</p>

IV, intravenous; PO, by mouth; PRN, as needed.

In this case report, Dr Long expanded the volume of EXPAREL with 20 mL of 0.25% bupivacaine HCl and 20 mL of normal saline. In his current practice, Dr Long admixes 20 mL of EXPAREL with 30 mL of 0.25% bupivacaine HCl and 30 mL of normal saline, for a total volume of 80 mL. Dr Long increased his volume by 20 mL to provide more thorough distribution of the liposomes into the surgical site.

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

INFILTRATION NOTES

Following implantation of the acetabular cup, 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) solution was infiltrated into the anterior capsule using a 21-gauge needle. Multiple injections were performed at the surgical site, with frequent aspiration to ensure EXPAREL solution was not injected intravascularly.

After closure of capsule, remaining 40 mL of EXPAREL solution was infiltrated into the following structures (see Figures 1 and 2):

- Short external rotators
- Posterior capsule
- Periosteum (anteriorly)
- Abductors
- Subcutaneous tissue around the incision

Care was taken not to inject too far posteriorly in order to avoid the peri-neural region.



Figure 1



Figure 2

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 Long is a paid consultant for Pacira BioSciences, Inc.