

Administration Case Report With EXPAREL

This case report represents the individual experience of Dr Mark Brzezienski 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.

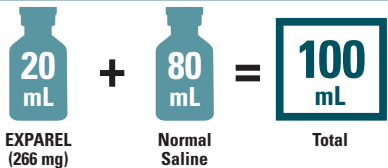
CASE INFORMATION

Physician Name	Mark Brzezienski, MD
Affiliation	The Plastic Surgery Group; Chattanooga, Tennessee
Surgical Case Performed	Delayed right latissimus dorsi breast reconstruction following mastectomy
Inpatient or Outpatient Procedure	Outpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	45 years of age
Patient History and Characteristics	Breast cancer; patient completed chemotherapy and radiation therapy 1 year prior to procedure

PROCEDURAL DETAILS

Incision Size	Harvest includes the latissimus dorsi muscle and a 14 x 8 cm cutaneous paddle. At the site of the breast, an incision approximately 14-cm in length is made and the entire mastectomy site is re-dissected.
Preoperative Analgesics Used	None
Intraoperative Analgesics Used	Mixed anesthesia with inhalational agents, narcotics, amnestics, and benzodiazepines
Dose of EXPAREL and Total Volume Used*	 <p>The diagram illustrates the volume calculation: a 20 mL vial of EXPAREL (266 mg) is added to an 80 mL vial of Normal Saline, resulting in a total volume of 100 mL. The EXPAREL vial is labeled '20 mL EXPAREL (266 mg)', the Normal Saline vial is labeled '80 mL Normal Saline', and the total is shown in a box labeled '100 mL Total'.</p>

*In this case report, Dr Brzezienski expanded the volume of EXPAREL with 80 mL of normal saline. In his current practice, Dr Brzezienski admixes 20 mL of EXPAREL with 30 mL of 0.5% bupivacaine HCl and 50 mL of normal saline for a total volume of 100 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 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

- Prior to making any incisions, a field block was achieved by injecting 100 mL of EXPAREL® (bupivacaine liposome injectable suspension) around the periphery of the dissection site in 20 mL aliquots.
 - A 16-gauge needle was used to make a small incision through which a Colman infusion cannula was placed to infiltrate the product. (see Figure 1)
 - 60 mL was infiltrated into the back in three 20 mL aliquots; close attention was paid when infiltrating the inferior portion of the dissection where the muscle is detached, as patients commonly note discomfort in that area. (see Figures 2 and 3)
 - 40 mL was infiltrated into the front of the dissection in two 20 mL aliquots; close attention was paid when infiltrating the axilla, which is also particularly tender following surgery. (see 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 Brzezienski is a paid consultant for Pacira Pharmaceuticals, Inc.