EXPAREL®
(bupivacaine liposome injectable suspension)

# Administration Case Report: Unilateral Mastectomy Breast Reconstruction

This case report represents the individual experience of Dr Risal S. Djohan, and is intended to demonstrate his methodology for using EXPAREL in a pectoral field block for patients undergoing unilateral mastectomy with breast reconstruction.

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 a local anesthetic that produces postsurgical analgesia in patients aged 6 years and older. It is administered via single-dose infiltration. When infiltrated into the surgical site, it produces local analgesia. It may also be infiltrated in the fascial plane to produce regional analgesia as a regional field block. Regional anesthetic techniques to produce regional analgesia include, but are not limited to, transversus abdominis plane (TAP) block, pectoralis (PEC) and serratus anterior plane (SAP) blocks, erector spinae plane (ESP) block, and quadratus lumborum (QL) block. EXPAREL may also be administered in adults as an interscalene brachial plexus nerve block, a sciatic nerve block in the popliteal fossa, and an adductor canal block to produce postsurgical regional analgesia.

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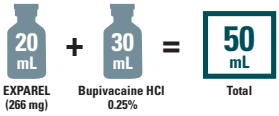
|---|---|
| **CASE INFORMATION** | |
| **Physician Name** | Risal S. Djohan, MD |
| **Specialty** | Plastic surgery |
| **Surgical Case Performed** | Unilateral mastectomy with breast reconstruction |
| **Inpatient or Outpatient Procedure** | Outpatient: same day surgery |
| **PATIENT CHARACTERISTICS** | |
| **Gender** | Female |
| **Age** | 48 years |
| **Patient History and Characteristics** | Right infiltrating ductal carcinoma |
| **PROCEDURAL DETAILS** | |
| **Incision Size** | 12-cm mastectomy incision |
| **Dose of EXPAREL and Total Volume Used** |  |
| **MULTIMODAL ANALGESIA PROTOCOL** | |
| **Preoperative Medications** | PO acetaminophen 1000 mg; scopolamine patch |
| **Intraoperative Medications** | 20 mL EXPAREL (266 mg) + 30 mL bupivacaine HCl 0.25%; IV dexamethasone 10 mg |
| **Postoperative Orders** | PO acetaminophen 1000 mg PRN q8h<br>Breakthrough moderate pain: PO oxycodone 5 to 10 mg, may repeat q5h<br>Breakthrough severe pain: IV morphine 1 mL (1 mg) PRN |
| **Discharge Medications** | PO ibuprofen 600 mg q8h, started prior to discharge and may be continued after discharge<br>Alternate PO ibuprofen 600 mg with PO acetaminophen 1000 mg for the next 3 to 5 days |

IV=intravenous; PO=by mouth; PRN=as needed; q5h=every 5 hours; q8h=every 8 hours.

The recommended dose of EXPAREL for infiltration in adults 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. The recommended dose of EXPAREL for patients aged 6 to <17 years old is 4 mg/kg, up to a maximum of 266 mg. The recommended dose of EXPAREL in adults for interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and adductor canal is 133 mg. The recommended dose of EXPAREL in adults for adductor canal block is 133 mg (10 mL) admixed with 50 mg (10 mL) of 0.5% bupivacaine HCl, for a total volume of 20 mL.

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 (which is approved for use in patients aged 12 and older) 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 the last page and refer to accompanying full Prescribing Information, which is also available at www.EXPARELpro.com.**

## INFILTRATION NOTES

### ASSESSED THE SIZE OF THE SURGICAL SITE AND DEPTH OF TISSUE, THEN PREPARED INJECTION MATERIALS ACCORDINGLY

In this procedure, Dr Djohan determined a total volume of 50 mL would be needed to cover the surgical site. He admixed 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 30 mL of 0.25% bupivacaine HCl. Bupivacaine HCl was added to provide early-onset analgesia to bridge the time to onset of the long-acting local analgesia provided by EXPAREL.

In a bilateral mastectomy, Dr Djohan expands with an additional 40 mL of normal saline, for a total volume of 90 mL of EXPAREL solution.

### DIVIDED INJECTATE INTO SYRINGES WITH NEEDLE SIZES APPROPRIATE FOR INFILTRATION (20- TO 25-GAUGE) AND PLANNED WHICH AREAS TO INFILTRATE WITH EACH INJECTION

For this procedure, Dr Djohan divided the 50 mL mixture of EXPAREL and bupivacaine into five 10 mL syringes, using 22-gauge needles, and infiltrated as follows:

### Step #1: Pectoralis Major

Dr Djohan infiltrated 15 mL of EXPAREL into the pectoralis major, starting at the lateral border of the muscle toward the axilla and infiltrating 1 mL every 1.0 to 1.5 cm. He also made sure to infiltrate into the medial aspects of the muscle and the surrounding nerve fibers.

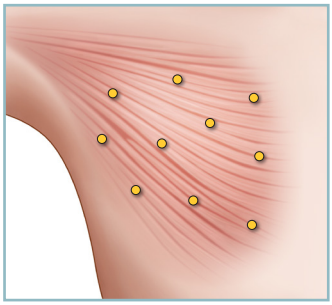


**FIGURE 1.** Pectoralis major muscle

### Step #2: Pectoralis Minor

He then infiltrated 3 to 5 mL of EXPAREL into the pectoralis minor. He infiltrated 0.5 to 1.0 mL every 1.0 to 1.5 cm, making sure to inject into the medial aspects of the muscle and surrounding nerve fibers.

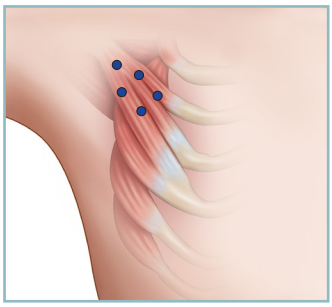


**FIGURE 2.** Pectoralis minor muscle

## INFILTRATION NOTES (cont)

### Step #3: Serratus Anterior

Dr Djohan then palpated the ribs underneath the serratus anterior muscle and infiltrated 2 to 3 mL of EXPAREL® (bupivacaine liposome injectable suspension) every 2 to 3 cm over each of the ribs. He infiltrated the serratus anterior muscle at different levels of ribs to create a wide field block that covered the lateral aspect of the chest wall for a total of 12 mL.

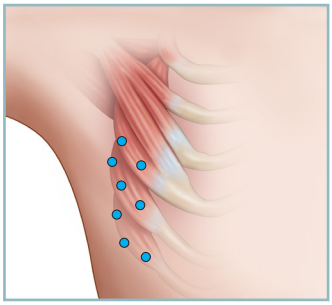


**FIGURE 3.** Serratus anterior muscle

### Step #4: Inframammary Fold

He infiltrated 1 to 2 mL of EXPAREL every 2 to 3 cm into the inframammary fold medially and laterally for a total of 5 to 8 mL.

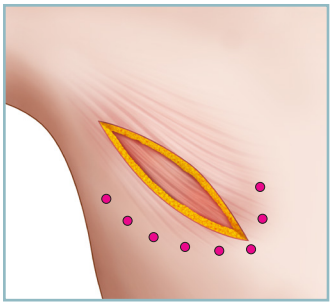


**FIGURE 4.** Inframammary fold

### Step #5: Lymph Node Biopsy Site or Axillary Dissection

After lymph node biopsy or dissection was performed, Dr Djohan infiltrated 5 mL into the medial aspect of the arm to form a field block around the axillary dissection or axillary surgical site.

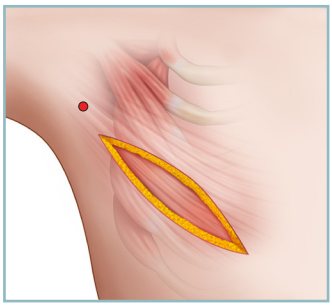


**FIGURE 5.** Axillary dissection

### Step #6: Drain Site

He identified/marked the surgical drain site. Then he injected 3 to 5 mL into the surrounding areas of the drain site and the path from drain site to the incision, then inserted the drains. He infiltrated any leftover EXPAREL into the external periphery of the breast.

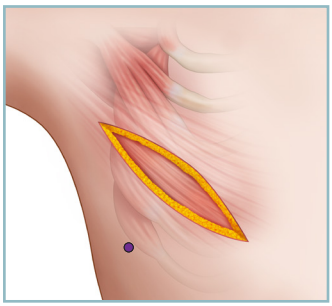
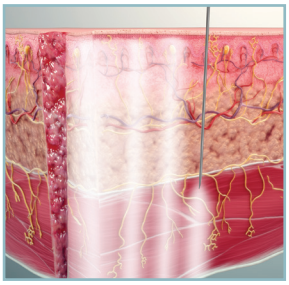


**FIGURE 6.** Surgical drain site

## INFILTRATION NOTES (cont)

### PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE



Dr Djohan infiltrated EXPAREL® (bupivacaine liposome injectable suspension) into all tissue layers using a moving needle technique. With a moving needle technique, the injections were spread in a fanlike pattern and occurred as the needle was both inserted and withdrawn to maximize the coverage area. This technique was systematically and meticulously repeated at each injection site, with overlapping diffusion of EXPAREL to ensure there were no gaps in analgesic coverage.

**Indication**

EXPAREL® (bupivacaine liposome injectable suspension) is indicated to produce postsurgical local analgesia via infiltration in patients aged 6 years and older and regional analgesia in adults via an interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and an adductor canal block. Safety and efficacy have not been established in other nerve blocks.

**Important Safety Information**

EXPAREL is contraindicated in obstetrical paracervical block anesthesia.

Adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via nerve block were nausea, pyrexia, headache, and constipation.

Adverse reactions with an incidence greater than or equal to 10% following EXPAREL administration via infiltration in pediatric patients six to less than 17 years of age were nausea, vomiting, constipation, hypotension, anemia, muscle twitching, vision blurred, pruritus, and tachycardia.

Do not admix lidocaine or other non-bupivacaine local anesthetics with EXPAREL. EXPAREL may be administered at least 20 minutes or more following local administration of lidocaine.

EXPAREL is not recommended to be used in the following patient populations: patients <6 years old for infiltration, patients younger than 18 years old for nerve blocks, 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, sciatic nerve block in the popliteal fossa, and adductor canal 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 Bowers is a paid consultant for Pacira BioSciences, Inc.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