Administration Case Report With EXPAREL

EXPAREL® (bupivacaine liposome injectable suspension) OPIOID FREE

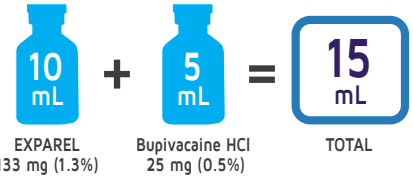
This case report represents the individual experience of Dr Jeffrey C. Gadsden and is intended to demonstrate his methodology for using EXPAREL in an interscalene brachial plexus nerve block.

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.

CASE INFORMATION	
Physician Name	Jeffrey C. Gadsden, MD
Affiliation	Duke University Medical Center Associate Professor of Anesthesiology Chief, Division of Orthopedic, Plastic, and Regional Anesthesiology
Nerve Block Performed	Interscalene brachial plexus nerve block
Inpatient or Outpatient Setting	Outpatient

PATIENT CHARACTERISTICS	
Gender	Female
Age	67 years
Patient History and Characteristics	History of controlled hypertension, but active and otherwise healthy. Has been experiencing increasing shoulder pain with limited range of motion for 2 years. Scheduled to have **arthroscopic rotator cuff repair** and subacromial decompression under combined ultrasound-guided interscalene brachial plexus block and general anesthesia, with laryngeal mask airway.

PROCEDURAL DETAILS	
Preoperative Analgesics Used	Acetaminophen 975 mg PO Celecoxib 400 mg PO Pregabalin 75 mg PO
Nerve Block Performed	Interscalene brachial plexus nerve block with 10 mL (133 mg) of EXPAREL admixed with 5 mL of 0.5% bupivacaine HCl
Dose of EXPAREL and Total Volume Used	

PO, by mouth.

The recommended dose of EXPAREL for interscalene brachial plexus nerve block is based upon one study of patients undergoing either total shoulder arthroplasty or rotator cuff repair. The maximum dose of EXPAREL for interscalene brachial plexus nerve block should not exceed 133 mg.

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

DR GADSDEN'S INTERSCALENE BRACHIAL PLEXUS NERVE BLOCK TECHNIQUE

Dr Gadsden performed an interscalene nerve block using ultrasound guidance to ensure accuracy of infiltration. With the patient in the lateral decubitus position (operative side up), a linear high-frequency ultrasound transducer was placed on the anteromedial aspect of the neck, approximately 2 cm above the clavicle, and the interscalene brachial plexus was identified between the anterior and middle scalene muscles.

After sterile preparation of the skin, a 21-gauge, 10-cm block needle was inserted in-plane from the lateral aspect of the transducer and directed through the middle scalene muscle. The needle was advanced until the tip was observed just lateral to the brachial plexus sheath (see Figure 1). After negative aspiration, an admixture of 10 mL of EXPAREL (133 mg) and 5 mL of 0.5% bupivacaine HCl (25 mg) was administered slowly with periodic aspiration, maintaining the needle tip position throughout.

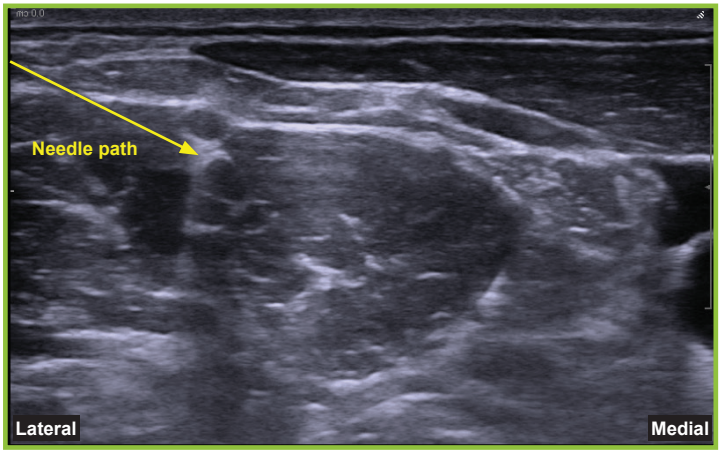


FIGURE 1. Interscalene brachial plexus nerve block ultrasound

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 Gadsden is a paid consultant for Pacira Pharmaceuticals, Inc.