Administration Case Report With EXPAREL

This case report represents the individual experience of Dr Gary F. Bouloux and is intended to demonstrate his methodology for using EXPAREL in a specific oral and maxillofacial procedure.

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 administration into the surgical site to produce postsurgical analgesia.

### CASE INFORMATION

<table>
<thead>
<tr>
<th>Physician Name</th>
<th>Gary F. Bouloux, MD, DDS, MDSc, FRACDS, FRACDS(OMS), FACS</th>
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</thead>
</table>
| Affiliation          | Associate Professor of Surgery, Division of Oral and Maxillofacial Surgery, Emory University  
                      | Chief of Oral and Maxillofacial Surgery, Director of Clinical Research, Grady Memorial Hospital |
| Surgical Case Performed | Bilateral temporomandibular joint arthroplasty with left disc plication and right discectomy with fat graft |
| Inpatient or Outpatient Procedure | Inpatient |

### PATIENT CHARACTERISTICS

<table>
<thead>
<tr>
<th>Gender</th>
<th>Female</th>
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<tbody>
<tr>
<td>Age</td>
<td>55 years</td>
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<tr>
<td>Patient History and Characteristics</td>
<td>Long-standing bilateral temporomandibular joint pain. Patient had tried conservative treatment for 12 months with little improvement in pain, and surgery was determined to be the best option at consultation</td>
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<td>Pathology</td>
<td>Temporomandibular joint arthralgia with degenerative joint disease</td>
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### PROCEDURAL DETAILS

| Incision Size | 40 mm |
| Preoperative Analgesics Used | 5 mL 0.5% bupivacaine HCl with epinephrine |
| Intraoperative Analgesics Used | Toradol IV  
12 mL 0.5% bupivacaine HCl with epinephrine to induce great auricular, auriculotemporal, and zygomaticotemporal nerve blocks  
40 mL expanded EXPAREL for local infiltration* |
| Dose of EXPAREL and Total Volume Used | ![](image)  
EXPAREL (266 mg) + Normal Saline (20 mL) = Total (40 mL) |

*IV, intravenous.

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 undiluted (20 mL) or diluted 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 toxicity. Other than with bupivacaine HCl, 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.
Step #1: Great auricular, auriculotemporal, and zygomaticotemporal nerve blocks

Step #2: Beneath the earlobe

Step #3: Medial capsule and lateral pterygoid muscle

Step #4: Temporalis muscle and auricle

Step #5: Along anterior and posterior aspects of incision site

Step #6: Behind condyle

NERVE BLOCKS WITH BUPIVACAINE HCl

3 mL of 0.5% bupivacaine HCl with epinephrine were injected into the great auricular nerve to provide anesthesia to the inferior aspect of the incision site.

2 mL of 0.5% bupivacaine HCl with epinephrine were injected behind the neck of the condyle into the auriculotemporal nerve.

1 mL of 0.5% bupivacaine HCl with epinephrine was injected into the zygomaticotemporal nerve as it exits medial to the zygomatic arch.

LOCAL INFILTRATION WITH EXPAREL

2 mL of expanded EXPAREL were infiltrated beneath the earlobe at a depth of 10 mm.

4 mL of expanded EXPAREL were infiltrated into the medial capsule and lateral pterygoid muscle.

3 mL of expanded EXPAREL were infiltrated into the belly of the temporalis muscle and into the auricle.

10 mL of expanded EXPAREL were infiltrated along the anterior and posterior aspects of the incision at a depth of about 7 to 8 mm per injection.

1 mL of expanded EXPAREL was infiltrated posterior and medial to the mandibular condyle, 15 mm below the superior surface of the condyle.

When injecting along the incision, infiltrate parallel to the cut edge of tissue until there is visible swelling. This step may need to be repeated at a depth of 15 mm in the anterior aspect of the incision if the tissue is thick.

Once completed, infiltration steps were repeated on the other side with the remaining 20 mL of expanded EXPAREL.
PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE

Dr Bouloux infiltrated EXPAREL into all tissue layers using a moving needle technique. With a moving needle technique, the injections were spread in a fan-like 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.

Important Safety Information

EXPAREL is contraindicated in obstetrical paracervical block anesthesia.

In clinical trials, the most common adverse reactions (incidence ≥10%) following EXPAREL administration were nausea, constipation, and vomiting.

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. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations.

Warnings and Precautions Specific to EXPAREL

EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks, or intravascular or intra-articular use.

Non-bupivacaine-based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more. Formulations of bupivacaine other than EXPAREL should not be administered within 96 hours following administration of EXPAREL.

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 paresthesias. 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 Bouloux is a paid consultant for Pacira Pharmaceuticals, Inc.