Administration Case Report With EXPAREL

This case report represents the individual experience of Dr Peter Whang and is intended to demonstrate his methodology for using EXPAREL in a specific spinal 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>Peter G. Whang, MD, FACS</th>
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</thead>
<tbody>
<tr>
<td>Affiliation</td>
<td>Yale University School of Medicine</td>
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<tr>
<td>Surgical Case Performed</td>
<td>Two-level open laminectomy and posterior spinal fusion (L3-L5)</td>
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<tr>
<td>Inpatient or Outpatient Procedure</td>
<td>Inpatient</td>
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</tbody>
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### PATIENT CHARACTERISTICS

<table>
<thead>
<tr>
<th>Gender</th>
<th>Male</th>
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<tbody>
<tr>
<td>Age</td>
<td>34 years</td>
</tr>
<tr>
<td>Patient History and Characteristics</td>
<td>Bilateral leg claudication Multiple risk factors for ORAE—chronic narcotic use, obesity</td>
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<tr>
<td>Pathology</td>
<td>L3-L5 spondylosis with stenosis</td>
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### PROCEDURAL DETAILS

<table>
<thead>
<tr>
<th>Incision Size</th>
<th>12 cm</th>
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<tbody>
<tr>
<td>Preoperative Analgesics Used</td>
<td>GETA 10 mL of 0.25% bupivacaine HCl with epinephrine</td>
</tr>
<tr>
<td>Intraoperative Analgesics Used</td>
<td>90 mL expanded EXPAREL</td>
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**Dose of EXPAREL and Total Volume Used**

\[
\begin{align*}
20 \text{ mL} & \quad \text{EXPAREL} \quad (266 \text{ mg}) \\
20 \text{ mL} & \quad \text{Bupivacaine HCl} \quad 0.5\% \\
50 \text{ mL} & \quad \text{Normal Saline} \\
\text{Total} & \quad 90 \text{ mL}
\end{align*}
\]

GETA, general endotracheal anesthesia; ORAE, opioid-related adverse events.

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.
**INFECTION NOTES**

**Step #1:**
Two-thirds of the solution is infiltrated circumferentially below the fascia, above and below the paraspinous muscles.

**Step #2:**
The remaining one-third is infiltrated circumferentially into the subcuticular/subcutaneous space.

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**ASSESS THE SIZE OF THE SURGICAL SITE AND DEPTH OF TISSUE, THEN PREPARE INJECTION MATERIALS ACCORDINGLY**

In this procedure, Dr. Whang determined a total volume of approximately 90 mL would be needed to cover the surgical site. He expanded 20 mL of EXPAREL with 50 mL of normal saline and admixed this solution with 20 mL of 0.5% bupivacaine HCl. Bupivacaine HCl was added to provide short-term local analgesia in the postanesthesia care unit that overlapped with the long-term local analgesia provided by EXPAREL.

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**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. Whang divided the injectate into four 20-mL syringes and one 10-mL syringe using 22-gauge needles and infiltrated as follows:

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**INFECTION NOTES (cont)**

**Step #1:**
Dr. Whang infiltrated 68 mL of expanded EXPAREL circumferentially around the incision into the subfascial layer above and below the paraspinous muscles. He injected 1 to 2 mL every 1.0 to 1.5 cm along the incision to ensure more complete analgesic coverage of the surgical site.

**Step #2:**
Starting at the apex, Dr. Whang infiltrated 30 mL of expanded EXPAREL circumferentially around the incision into the subdermal and subcutaneous tissues. He injected 1 to 2 mL every 1.0 to 1.5 cm along the incision.

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**FIGURE 1. Subfascial layer**

**FIGURE 2. Subdermal and subcutaneous tissues**

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**One-Level Procedure:**
EXPAREL 266 mg (20 mL) + Bupivacaine HCl 0.5% (20 mL) + Normal Saline (20 mL) = Total Volume of 60 mL

**Two-Level Procedure:**
EXPAREL 266 mg (20 mL) + Bupivacaine HCl 0.5% (20 mL) + Normal Saline (50 mL) = Total Volume of 90 mL

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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.
**Important Safety Information**

EXPAREL is contraindicated in obstetrical paracervical block anesthesia.

In clinical trials, the most common adverse reactions (incidence $\geq 10\%$) 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 Whang is a paid consultant for Pacira Pharmaceuticals, Inc.