

Administration Case Report With EXPAREL

This case report represents the individual experiences of Dr Alok Sharan and Dr Daniel Nekola, and is intended to demonstrate their methodology for using EXPAREL in a specific spinal procedure.

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 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.

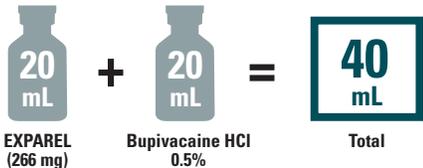
CASE INFORMATION

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| Physician Names | Alok Sharan, MD, MHCDS | Daniel Nekola, MD |
| Affiliation | Orthopedic Spine Surgery Director, Spine and Orthopedics NJ Spine and Wellness Old Bridge, NJ | Anesthesiology Maimonides Medical Center Department of Neuroanesthesia Brooklyn, NY |
| Surgical Case Performed | Minimally invasive transforaminal lumbar interbody fusion (TLIF) with a thoracolumbar interfascial plane (TLIP) block | |
| Inpatient or Outpatient Procedure | Outpatient | |

PATIENT CHARACTERISTICS

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| Gender | Male |
| Age | 39 years |
| Patient History and Characteristics | Patient previously underwent microdiscectomy for a herniated disk. He presented with a reherniated disk 1 year later. Based on the patient's labor-intensive occupation, he elected to have a lumbar fusion. |

PROCEDURAL DETAILS

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| Incision Size | 4-cm bilateral Wiltse incision |
| Dose of EXPAREL and Total Volume Used |  <p>EXPAREL (266 mg) + Bupivacaine HCl (0.5%) = Total 40 mL</p> |
| Intraoperative Anesthesia | Spinal anesthesia; 10 mg to 15 mg isobaric bupivacaine 0.5%/25 ug fentanyl |

MULTIMODAL ANALGESIA AND ENHANCED RECOVERY AFTER SURGERY PROTOCOL

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| Preoperative Medications Used | PO oxycodone 10 mg, PO acetaminophen 650 mg (optional), PO gabapentin 300 mg (optional) |
| Intraoperative Medications Used | EXPAREL in addition to spinal anesthesia EXPAREL TLIP block |
| Postoperative Medications Used | PO diazepam 2.5 mg q6hr PRN for the first 24 hours, PO oxycodone 5 mg or 10 mg/acetaminophen 325 mg q4hr PRN moderate or severe breakthrough pain |

PO, by mouth; PRN, pro re nata (as the situation demands); q4hr, every 4 hours; q6hr, every 6 hours.

Please see Important Safety Information on reverse and refer to accompanying full Prescribing Information for complete Dosage and Administration information before using EXPAREL.

Dr Nekola performed a TLIP block using ultrasound guidance. The patient was in the prone position on a Jackson Table. For the TLIP block, Dr Nekola determined that a total volume of 40 mL would be needed. He admixed 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 20 mL of 0.5% bupivacaine HCl.



Step #1:

Dr Nekola started by identifying the surgical level, the L4 vertebra. He placed the 1-in linear ultrasound probe across the level of the L4 vertebra to identify the spinous process at L4. He then moved laterally to the right to visualize the multifidus muscle. He identified the transverse process inferior to these muscular structures.

Step #2:

After a negative aspiration, Dr Nekola infiltrated 20 mL of the EXPAREL admixture at the interface between the multifidus muscle and the longissimus muscle. He also directed the infiltrate toward the posterior fascial planes of those muscles. Once completed, he repeated this on the left side of the L4 vertebra.



Dr Nekola uses a 100-mm hyperechoic needle to ensure adequate visualization on the ultrasound monitor and to provide sufficient needle depth to reach the interface between muscles.

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 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 neurologic and cardiovascular effects related to local anesthetic systemic toxicity. Other than with bupivacaine, EXPAREL should not be admixed with other drugs prior to administration.

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. **Methemoglobinemia:** Cases of methemoglobinemia have been reported with local anesthetic use.

Disclosure: Drs Sharan and Nekola are paid consultants for Pacira BioSciences, Inc.