

Administration Case Report With EXPAREL

This case report represents the individual experience of Dr Michael Y. Wang 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 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

Physician Name	Michael Y. Wang, MD, FACS
Affiliation	Director of Neurosurgery Lois Pope LIFE Center Department of Neurosurgery Miami, FL
Surgical Case Performed	Percutaneous posterior 1-level lumbar fusion with VIPER PRIME™ System
Inpatient or Outpatient Procedure	Inpatient

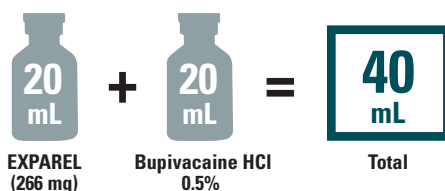
PATIENT CHARACTERISTICS

Gender	Male
Age	79 years
Patient History and Characteristics	Patient had L4-L5 spondylolisthesis and spinal stenosis. He presented with intractable back and leg pain for which he had failed conservative measures and elected to have surgical treatment

PROCEDURAL DETAILS

Incision Size	2-cm incision lateral to the facet joint to access Kambin's triangle
Preoperative Medications Used	Ondansetron, pantoprazole
Preoperative Analgesics Used	None
Intraoperative Analgesics Used	MAC anesthesia: ketamine, propofol, dexmedetomidine, lidocaine HCl, EXPAREL, bupivacaine HCl, and midazolam

Dose of EXPAREL and Total Volume Used



MAC, monitored anesthesia care.
VIPER PRIME™ System is a trademark of DePuy Synthes Companies.

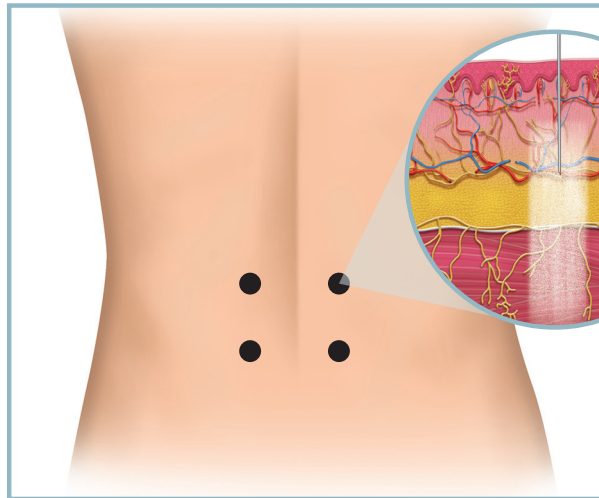
The recommended dose of EXPAREL is based on the size of the surgical site, the volume required to cover the area, and individual patient factors that may impact the safety of an amide local anesthetic. The maximum dose of EXPAREL should not exceed 266 mg.

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 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 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.

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

DR WANG'S INFILTRATION NOTES



■ Step #1:

Dr Wang inserted a spinal needle into the screw track under direct visualization. He then infiltrated 10 mL of the EXPAREL® (bupivacaine liposome injectable suspension) injectate, injecting as he withdrew. He injected under pressure to mechanically force EXPAREL to diffuse into the tissues, ensuring analgesic coverage along the length of the screw track.

■ Step #2:

Dr Wang repeated this method for each of the other 3 screw tracks.



Dr Wang used an 18-gauge needle because it is stiffer, allowing for better steering when placing the needle into the screw track.



Watch Dr Wang infiltrate with EXPAREL at www.EXPAREL.com

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.