The pivotal trials for adductor canal block and sciatic nerve block in the popliteal fossa showed that EXPAREL is superior to bupivacaine HCl[1,2]

EXPAREL®
(bupivacaine liposome injectable suspension)

Adductor canal block pivotal trial

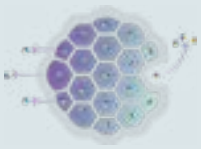
Treatment with EXPAREL admixed with bupivacaine hydrochloride (HCl) resulted in **statistically significant improvements in pain intensity scores (*P*=0.0074)** and opioid consumption (*P*=0.0071) **through 4 days compared with bupivacaine HCl alone.[1]***

Sciatic nerve block in the popliteal fossa pivotal trial

Treatment with EXPAREL demonstrated a **highly statistically significant 44% reduction in pain intensity scores through 4 days versus bupivacaine HCl (*P*<0.00001)**.
In addition, a 61% reduction in total opioid consumption (*P*<0.00001) was observed through 4 days postsurgery with EXPAREL.[2†]

Explore the innovation behind the evidence

EXPAREL is a long-lasting, non-opioid option that provides postsurgical analgesia by encapsulating bupivacaine in a proprietary multivesicular liposome (pMVL) technology. This advanced delivery technology enables greater pain control with a similar safety profile to bupivacaine HCl.[1,2]



The benefits of pMVL:

- Releases controlled levels of bupivacaine over time[3]
- Extends analgesic duration while reducing the need for opioids[‡]
- Eliminates the need for catheters and pumps that may hinder recovery[4]

Explore additional results from the adductor canal block pivotal trial and the sciatic nerve block in the popliteal fossa pivotal trial

*The adductor canal block pivotal trial investigated EXPAREL admixed with bupivacaine HCl versus bupivacaine HCl alone, administered as an adductor canal block (ACB) for total knee arthroplasty (TKA). Prior to the surgical procedure, patients received 133 mg (10 mL) of EXPAREL admixed with 50 mg (10 mL) of 0.5% bupivacaine HCl OR 50 mg (10 mL) of 0.5% bupivacaine HCl mixed with 10 mL normal saline via saphenous nerve (adductor canal) block. All patients also received 37.5 mg (15 mL) of 0.25% immediate-release bupivacaine HCl as an infiltration between the popliteal artery and capsule of the knee (IPACK) block immediately following study drug administration. Frequency of adverse events (AEs) was similar between the EXPAREL and bupivacaine HCl groups; most AEs were mild to moderate in severity. The most common AEs (>10%) in the EXPAREL group were nausea, constipation, muscle spasms, and headache[1]; †The sciatic nerve block in the popliteal fossa pivotal trial investigated EXPAREL versus bupivacaine HCl administered via sciatic nerve block in the popliteal fossa in participants undergoing bunionectomy, a common and well-validated surgical model often used to study postsurgical pain for foot & ankle procedures. Prior to the surgical procedure, patients received 133 mg of EXPAREL mixed with 20 mL saline OR 50 mg (20 mL) of 0.25% bupivacaine HCl mixed with 10 mL saline via sciatic nerve block in the popliteal fossa. All patients received 100 mg (20 mL) of 0.5% immediate-release bupivacaine HCl as a Mayo field block after study drug administration. The frequency of adverse events (AEs) was similar across treatment groups, with all AEs being mild or moderate in severity. The most common AEs (>10%) following EXPAREL administration were nausea and constipation[2]; ‡The clinical benefit of the decrease in opioid consumption was not demonstrated in the pivotal trials.

Please see Important Safety information on the next page and full Prescribing Information at www.EXPAREL.com.

Indication

EXPAREL® (bupivacaine liposome injectable suspension) is indicated to produce postsurgical local analgesia via infiltration in patients aged 6 years and older and regional analgesia in adults via an interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and an adductor canal block. Safety and efficacy have not been established in other nerve blocks.

Important Safety Information

EXPAREL is contraindicated in obstetrical paracervical block anesthesia.

Adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via nerve block were nausea, pyrexia, headache, and constipation.

Adverse reactions with an incidence greater than or equal to 10% following EXPAREL administration via infiltration in pediatric patients six to less than 17 years of age were nausea, vomiting, constipation, hypotension, anemia, muscle twitching, vision blurred, pruritus, and tachycardia.

Do not admix lidocaine or other non-bupivacaine local anesthetics with EXPAREL. EXPAREL may be administered at least 20 minutes or more following local administration of lidocaine.

EXPAREL is not recommended to be used in the following patient populations: patients <6 years old for infiltration, patients younger than 18 years old for nerve blocks, 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, sciatic nerve block in the popliteal fossa, and adductor canal 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.

Full Prescribing Information is available at www.EXPAREL.com.

For more information, please visit www.EXPAREL.com or call 1-855-793-9727.

REFERENCES: 1. Gadsden J, Hamilton M, Schwartz G, et al. Liposomal bupivacaine via adductor canal block after total knee arthroplasty: a randomized, double-blind, phase 3 trial. Poster presented at: 48th Annual Regional Anesthesiology and Acute Pain Medicine Meeting; April 20, 2023; Hollywood, FL. Poster 4381. **2.** Schwartz G, Gadsden J, Gonzales J, et al. Liposomal bupivacaine via sciatic nerve block after bunionectomy: a randomized, double-blind, active-controlled, phase 3 trial. Poster presented at: 48th Annual Regional Anesthesiology and Acute Pain Medicine Meeting; April 20, 2023: Hollywood, FL. Poster 4377. **3.** Bramlett K, Onel E, Viscusi ER, Jones K. A randomized, double-blind, dose-ranging study comparing wound infiltration of DepoFoam bupivacaine, an extended-release liposomal bupivacaine, to bupivacaine HCl for postsurgical analgesia in total knee arthroplasty. *Knee*. 2012;19(5):530-536. **4.** Grissinger M. Improved safety needed in handling elastomeric reservoir balls used for pain relief. *P T*. Accessed November 3, 2023. https://pubmed.ncbi.nlm.nih.gov/23946616/

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