



FAST FACTS

ADVANCING RECOVERY WITH LONG-LASTING NON-OPIOID POSTSURGICAL PAIN CONTROL

THE FIRST AND ONLY FDA-APPROVED LONG-LASTING LOCAL ANALGESIC FOR AGES 6 AND ABOVE

EXPAREL is available as 20 mL (266 mg) and 10 mL (133 mg) 1.3% concentration single-dose vials.

NDC 65250-266-20 EXC 65250-266-20 EXC

Indication

EXPAREL 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.

Please see Important Safety Information <u>on last page</u> and refer to full Prescribing Information, which is available at <u>www.EXPAREL.com</u>.

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



Single-dose, long-lasting EXPAREL as part of a multimodal approach, reduces postsurgical pain and can minimize the use of opioids*

• Eliminates the need for pumps and catheters thatcan hinder patient recovery¹



EXPAREL is different than other local analgesics

EXPAREL uses proprietary multivesicular liposome (pMVL) technology to extend analgesia.¹

DESIGNED

to deliver controlled levels of bupivacaine¹

COMPOSED

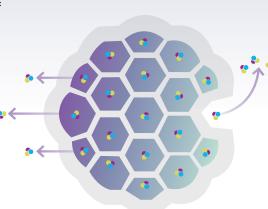
of naturally occurring, biocompatible lipids²⁻⁴

ENCAPSULATES the bupivacaine in

a suspension of multivesicular liposomes

RELEASES

bupivacaine over time¹



ACHIEVES

targeted analgesia at the surgical site

PROVIDES

safe, consistent levels of bupivacaine¹

ELIMINATES

the need for catheters and pumps that may hinder recovery⁵

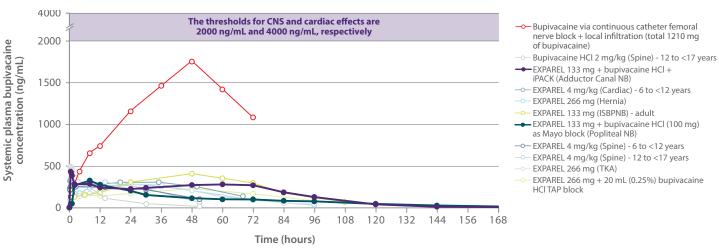
EXTENDS

analgesic duration while reducing the need for opioids*

*The clinical benefit of the decrease in opioid consumption was not demonstrated in the pivotal trials.



EXPAREL delivers a safe, consistent slow release of bupivacaine over time^{2†}



CNS=central nervous system; ISBPNB=interscalene brachial plexus nerve block; NB=nerve block; TAP=transversus abdominis plane; TKA=total knee arthroplasty.

[†]The rate of systemic absorption of bupivacaine is dependent upon the total dose of drug delivered, the route of administration, and the vascularity of the administration site. Systemic plasma levels of bupivacaine following administration of EXPAREL are not correlated with local efficacy.

B

EXPAREL is safe for use in breastfeeding patients



EXPAREL is versatile and can be used in a wide range of procedures across specialties in patients 6 years and older

Infiltration

Broad indication for infiltration across surgical procedures to provide local/regional analgesia

Field Blocks

• Indicated for a wide variety of blocks, including ESP, PEC, QL, and TAP

Nerve Blocks

 Indicated in adults as an interscalene brachial plexus nerve block, a sciatic nerve block in the popliteal fossa, and an adductor canal block to produce postsurgical regional analgesia

ESP=erector spinae plane; PEC=pectoralis; QL=quadratus lumborum; TAP=transversus abdominis plane.

EXPAREL is available in two vial sizes for dosing and administration flexibility

EXPAREL is available as 20 mL (266 mg) and 10 mL (133 mg), 1.3%-concentration single-use vials

- The 20 mL vial contains ~740 million liposomes to provide analgesic coverage in large surgical sites
- The 10 mL vial contains ~370 million liposomes to provide analgesic coverage in small surgical sites



Dosing for EXPAREL

Up to a maximum dose of 266 mg (20 mL), based on the following factors:

- · Size of the surgical site
- · Volume required to cover the area
- Individual patient factors that may impact the safety of an amide local anesthetic

For pediatric patients 6 to 17 years of age, dosing is weight based: 4 mg/kg For interscalene brachial plexus nerve block in adults the recommended dose is 133 mg (10 mL)

For sciatic nerve blocks in the popliteal fossa in adults the recommended dose is 133 mg (10 mL) and is based on a study of patients undergoing bunionectomy

For adductor canal blocks in adults the recommended dose is 133 mg (10 mL) admixed with 50 mg (10 mL) 0.5% bupivacaine HCl, for a total volume of 20 mL and is based on a study of patients undergoing total knee arthroplasty

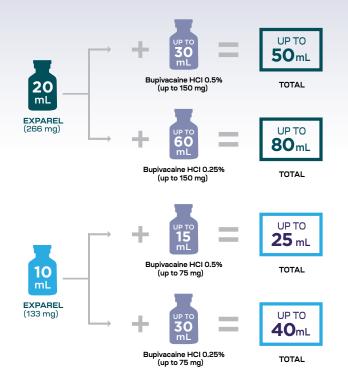


Admixing and/or expanding with EXPAREL

Admixing

To attain early analgesic onset, bupivacaine HCI⁺ may be admixed with EXPAREL

- The ratio of the milligram dose of bupivacaine HCl to EXPAREL must not exceed 1:2
- Admixing may impact the pharmacokinetic/pharmacodynamic properties of EXPAREL; this effect is concentration dependent



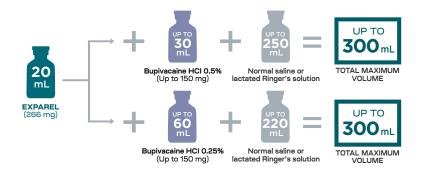
Expanding

To ensure optimal analgesic coverage in larger surgical sites, the volume of EXPAREL can be expanded with normal saline (0.9%) or lactated Ringer's solution

Maintain a minimum concentration of 0.89 mg/mL

Admixing and Expanding

Consider the amount of normal saline or lactated Ringer's solution, bupivacaine HCl, and EXPAREL as part of the total maximum volume



[†]Bupivacaine HCI is indicated for use in patients aged 12 years and older.

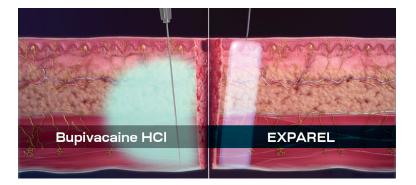


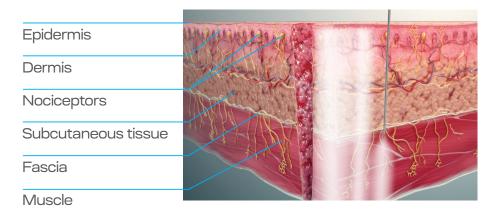


EXPAREL administration

EXPAREL is administered differently than bupivacaine HCl, allowing for precise delivery of analgesia.

- Use a frequent and consistent injection technique throughout the surgical site, into all tissue layers to ensure complete analgesic coverage
- Utilizing a moving needle technique, EXPAREL should be injected slowly (generally 1-2 mL per injection)
- Use a 25-gauge or a larger-bore needle to maintain the structural integrity of the liposomal bupivacaine particles
- Aspirate frequently to minimize risk of intravascular injection
- When infiltrating:
 - Inject the tissues of the surgical site using a deep tissue infiltration technique
 - Inject frequently in small areas 1-1.5 cm apart









Compatibility considerations

- EXPAREL should not be admixed with drugs other than bupivacaine prior to administration
- Wait 20 minutes after administering lidocaine or other non-bupivacainebased local anesthetics before administering EXPAREL into the same surgical site
- Allow topical antiseptics to dry before administering EXPAREL into the same surgical site
- Do not dilute EXPAREL with water or other hypotonic agents as it will result in disruption of the liposomal particles

Storage and handling recommendations

- The 133 mg (10 mL) and 266 mg (20 mL) doses of EXPAREL are available in cartons of 4 and 10 vials
- EXPAREL vials should be stored and refrigerated between 2°C to 8°C (36°F to 46°F)
- Sealed, intact (unopened) EXPAREL vials may be held at a controlled room temperature of 20°C to 25°C (68°F to 77°F) for up to 30 days. Vials should not be re-refrigerated
- EXPAREL should not be frozen
- EXPAREL should not be exposed to high temperatures (>40°C or 104°F) for an extended period
- Do not administer EXPAREL if it is suspected of having been frozen or exposed to high temperatures
- Vials should be visually inspected before use. Do not use the vial if the stopper is bulging
- Open vials of EXPAREL should be used within 4 hours
- Invert vials of EXPAREL multiple times to resuspend the particles immediately prior to withdrawal from the vial

References

 Grissinger M. P T. 2013;38(5):243-245.
 Bramlett K, et al. Knee. 2012;19(5):530-536.
 Angst MS, et al. Clin Pharmacokinet. 2006;45(12):1153-1176.
 Kohn FR, et al. Drug Deliv. 1998;5(2):143-151.
 Richard BM, Newton P, Ott LR, et al. J Drug Deliv. 2012;2012:962101.
 Marino J, et al. J Arthroplasty. 2019;34(3):495-500.
 Gadsen J, et al. Presented at: American Society for Regional Anesthesia (ASRA) 48th Annual Regional Anesthesiology and Acute Pain Medicine Meeting; April 20, 2023; Hollywood, FL.
 Schwartz, et al. Presented at: American Society for Regional Anesthesia (ASRA) 48th Annual Regional Anesthesiology and Acute Pain Medicine Meeting; April 20, 2023; Hollywood, FL.
 Schwartz, et al. Dresented at: American Society for Regional Anesthesia (ASRA) 48th Annual Regional Anesthesiology and Acute Pain Medicine Meeting; April 20, 2023; Hollywood, FL.
 Schwartz, et al. J Clin Anesth. 2021;75:110503.
 Hu D, et al. Clin Drug Investig. 2013;33(2):109-115.
 Patel MA, et al. Pain Med. 2020;21(2):387-400.
 Mustafa HJ, et al. Obstet Gynecol. 2020;36(1):70-76.



INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

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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 intraarticular infusion of local anesthetics, which is an unapproved use.

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

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Full Prescribing Information is available at <u>www.EXPAREL.com</u>.



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