Bupivacaine Extended-Release Liposome Injection for Prolonged Postsurgical Analgesia in Patients Undergoing Hemorrhoidectomy:

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial

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Bupivacaine Extended-Release Liposome Injection for Prolonged Postsurgical Analgesia in Patients Undergoing Hemorrhoidectomy: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial

Gorfine SR, Onel E, Patou G, Krivokapic ZV.
Dis Colon Rectum. 2011;54(12):1552-1559.

Study Objective:

To compare the magnitude and duration of postsurgical analgesia from a single dose of EXPAREL® (bupivacaine liposome injectable suspension) with placebo administered intraoperatively in patients undergoing hemorrhoidectomy.

Study Design:

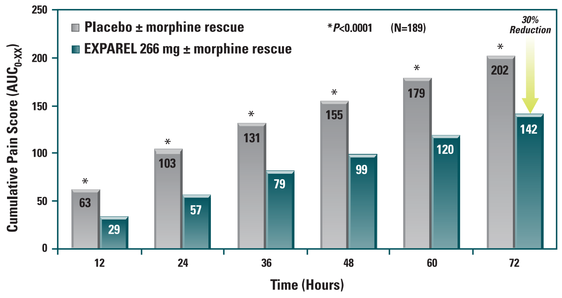
- Phase 3 multicenter, randomized, double-blind, parallel-group, placebo-controlled study
- Patients 18-86 years of age who were scheduled to undergo 2- or 3-column excisional hemorrhoidectomy under general anesthesia using the Milligan-Morgan technique
- Patients were randomized to receive 266 mg EXPAREL diluted to a total volume of 30 mL or 30 mL placebo (0.9% sodium chloride) via deep tissue infiltration at the end of surgery
  - EXPAREL contains free-base bupivacaine, not bupivacaine HCl; 266 mg EXPAREL is chemically equivalent to 300 mg bupivacaine HCl
- Postsurgical analgesia for breakthrough pain was available to patients in both groups and consisted of morphine sulfate 10 mg administered intramuscularly every 4 to 6 hours as needed for 72 hours
- Efficacy was measured as
  - **Pain control**, assessed by cumulative pain score (area under the curve for numeric rating scale scores) at multiple time points through 72 hours after study drug administration
  - **Opioid use**, including the proportion of patients avoiding supplemental opioid rescue medication, the amount of postsurgical opioids used, and the time to first opioid use

Study Results:

Significant Pain Control

30% Reduction in Cumulative Pain Score With EXPAREL

Cumulative pain scores through 72 hours in hemorrhoidectomy surgery

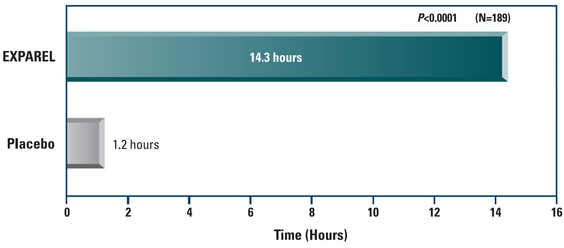


EXPAREL is indicated for administration into the surgical site to produce postsurgical analgesia.

Significant Reduction in Opioid Use

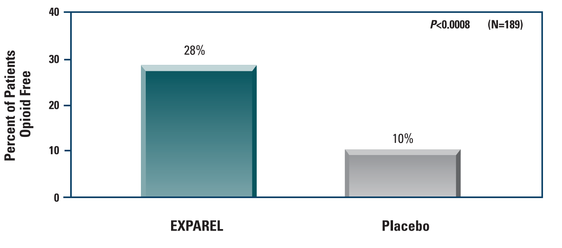
More Than a 12-Fold Increase in the Median Time to First Opioid Use With EXPAREL

Median time to first opioid use



Nearly 3 Times as Many Patients Avoided Opioid Use With EXPAREL

Percentage of patients who received no opioid medication through 72 hours



The clinical benefit of the attendant decrease in opioid consumption was not demonstrated.

Safety Results:

The overall incidence of treatment-emergent adverse events in this study was similar between the EXPAREL and placebo groups, with the majority of adverse events being mild in severity.

The most frequently reported treatment-emergent adverse events were anal hemorrhage and painful defecation.

Conclusions:

- A single injection of EXPAREL given at the end of a hemorrhoidectomy procedure using the Milligan-Morgan technique demonstrated a statistically significant reduction in cumulative pain scores through 72 hours, decreased opioid use, and delayed time to first opioid use
- EXPAREL may be a potentially useful therapeutic option for pain management after hemorrhoidectomy

Important Safety Information:

EXPAREL is contraindicated in obstetrical paracervical block anesthesia. EXPAREL has not been studied for use in patients younger than 18 years of age. 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. Other formulations of bupivacaine should not be administered within 96 hours following administration of EXPAREL. Monitoring of cardiovascular and neurological status, as well as vital signs should be performed during and after injection of EXPAREL as with other local anesthetic products. 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. In clinical trials, the most common adverse reactions (incidence ≥10%) following EXPAREL administration were nausea, constipation, and vomiting.

Please see the full Prescribing Information for EXPAREL.

www.EXPAREL.com

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EXPAREL®
(bupivacaine liposome injectable suspension)