## Exparel® (bupivacaine) – Expanded indication

- On March 22, 2021, Pacira BioSciences announced the FDA approval of Exparel (bupivacaine), in patients aged 6 years and older for single-dose infiltration to produce postsurgical local analgesia.
    - Exparel was previously approved for this indication in adults only.
- Exparel is also approved in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.
- The approval of Exparel for the expanded indication was based on a randomized, open-label study evaluating the pharmacokinetics and safety of Exparel in 95 pediatric patients aged 6 to less than 17 years who were undergoing spine or cardiac surgery. The efficacy of Exparel for local infiltration for pediatric patients (6 to less than 17 years of age) was extrapolated from the efficacy of Exparel for local infiltration for adults.
- The most common adverse reactions (≥ 10%) with Exparel use in pediatric patients six to less than 17 years of age were nausea, vomiting, constipation, hypotension, anemia, muscle twitching, blurred vision, pruritis, and tachycardia.
- The recommended dose of Exparel in pediatric patients is 4 mg/kg (up to a maximum of 266 mg) as a single-dose infiltration. The dose is based upon two studies of pediatric patients undergoing either spine surgery or cardiac surgery.
    - Refer to the Exparel drug label for dosing in adults and for complete injection instructions.