

## Caldolor<sup>®</sup> (ibuprofen) – Expanded indication

- On May 11, 2023, the FDA approved Cumberland Pharmaceuticals' [Caldolor \(ibuprofen\)](#) injection, in adults and pediatric patients aged 3 months and older for the:
  - Management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics
  - Reduction of fever.
- Caldolor was previously approved for these indications in patients aged 6 months and older.
- Caldolor carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.
- The recommended dose of Caldolor for pediatric patients ages 3 months to less than 6 months is a single dose at 10 mg/kg intravenously up to a maximum single dose of 100 mg. Infusion time must be at least 10 minutes.
  - Refer to the Caldolor drug label for dosing for older patients.