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Caldolor gains FDA nod for infant treatment

Cumberland Pharmaceuticals Inc., a specialty pharmaceutical company, announced that the U.S. Food and Drug Administration has approved expanded labeling for Caldolor, an intravenously delivered formulation of ibuprofen, to now include use in infants.

The nonnarcotic agent may now be administered for the treatment of pain and fever in patients three months to six months of age.

The newly FDA-approved label includes information regarding the product's indications and usage, appropriate patient populations, clinical study results, potential side effects, patient safety details, and instructions for use in these young children.

To support this expanded use of Caldolor, Cumberland sponsored a multi-center study in 21 hospitalized infants. All but one patient was treated with a single dose of the product.

The safety and efficacy of Caldolor has now been established for the treatment of pain and fever in pediatric patients aged 3 months and older. Use of Caldolor for these indications is supported by evidence from one adequate and controlled open label study in infants, along with additional safety data from four studies in 164 pediatric patients, supportive pediatric data from other approved ibuprofen products, and evidence from adequate and well-controlled studies in adults.

Importantly with this newly approved labeling, Caldolor is the only non-opioid product approved to treat pain in infants that is delivered through injection.