CALDOLOR®
(ibuprofen) Injection

Dosing Guidelines Chart[1-2]

Patient Weight (kg)	Ibuprofen Dose (mg)	Recommended Volume of IV Fluid (mL)	Volume of IV Ibuprofen Added (mL)
10	100	50	1
11	110	50	1.1
12	120	50	1.2
13	130	50	1.3
14	140	50	1.4
15	150	50	1.5
16	160	100	1.6
17	170	100	1.7
18	180	100	1.8
19	190	100	1.9
20	200	100	2
21	210	100	2.1
22	220	100	2.2
23	230	100	2.3
24	240	100	2.4
25	250	100	2.5
26	260	100	2.6
27	270	100	2.7
28	280	100	2.8
29	290	100	2.9
30	300	100	3
31	310	100	3.1
32	320	100	3.2
33	330	150	3.3
34	340	150	3.4
35	350	150	3.5
36	360	150	3.6
37	370	150	3.7
38	380	150	3.8
39	390	150	3.9
40	400	150	4

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Non-steroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
- CALDOLOR is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Bleeding, Ulceration and Perforation

- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

INDICATIONS AND USAGE[1]

CALDOLOR is indicated in adults and pediatric patients 6 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

IMPORTANT DOSAGE AND ADMINISTRATION INSTRUCTIONS

CALDOLOR must be diluted prior to administration.

Do not exceed 3,200 mg total daily dose in adults. Do not exceed 40 mg/kg or 2,400 mg, whichever is less, total daily dose in pediatric patients less than 17 years of age.

CONTRAINDICATIONS

CALDOLOR is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to ibuprofen or any components of the drug product and in patients who have a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients. CALDOLOR is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

CALDOLOR should be used with caution in patients with known cardiovascular (CV) disease or risk factors for CV disease, a history of peptic ulcer disease and/or GI bleeding, liver disease or symptoms of, hypertension and heart failure. When used in such patients, attention to using the lowest effective dose for the shortest time period is important to reduce the risk of serious adverse reactions. Avoid use in pregnant women starting at 30 weeks gestation.

ADVERSE REACTIONS

The most common adverse reactions are nausea, flatulence, vomiting, headache, hemorrhage and dizziness (>5%). The most common adverse reactions in pediatric patients are infusion site pain, vomiting, nausea, anemia and headache (≥2%).

1. Caldolor [Packet Insert]. Nashville TN: Cumberland Pharmaceutical Inc.; 2015
2. Data on file, Cumberland Pharmaceuticals Inc.

Please see www.caldolor.com for full prescribing information including boxed warning.

CUMBERLAND® PHARMACEUTICALS