CALDOLOR®
(ibuprofen) Injection

Pediatric Dosing Guide For Ready-to-Use Bag

Pediatric Dose: For pediatric patients between 6 months to 12 years, a single dose is 10 mg/kg intravenously up to a maximum single dose of 400 mg every 4 to 6 hours as necessary (see chart below). Infusion time must be at least 10 minutes. Maximum daily dose is 40 mg/kg or 2,400 mg, whichever is less. For pediatric patients between 12 and 17 years of age, a single does is 400 mg intravenously every 4 to 6 hours with a maximum daily dose of 2,400 mg and an infusion time of at least 10 minutes.

Weight		Ibuprofen	Recommended
kg	lbs.	Dose (mg)	Bag Volume (mL)
10	22	100	25
11	24	110	28
12	26	120	30
13	29	130	33
14	31	140	35
15	33	150	38
16	35	160	40
17	37	170	43
18	40	180	45
19	42	190	48
20	44	200	50
21	46	210	53
22	49	220	55
23	51	230	58
24	53	240	60
25	55	250	63
26	57	260	65
27	60	270	68
28	62	280	70
29	64	290	73
30	66	300	75
31	68	310	78
32	71	320	80
33	73	330	83
34	75	340	85
35	77	350	88
36	79	360	90
37	82	370	93
38	84	380	95
39	86	390	98
40	88	400	100

41	90	410	103
42	93	420	105
43	95	430	108
44	97	440	110
45	99	450	113
46	101	460	115
47	104	470	118
48	106	480	120
49	108	490	123
50	110	500	125
51	112	510	128
52	115	520	130
53	117	530	133
54	119	540	135
55	121	550	138
56	123	560	140
57	126	570	143
58	128	580	145
59	130	590	148
60	132	600	150

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 *[see Warnings and Precautions].***
- **CALDOLOR is contraindicated in the setting of coronary artery bypass graft (CABG) surgery *[see Contraindications (4) and Warnings and Precautions].***

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

CALDOLOR® (ibuprofen) Injection 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 SAFETY INFORMATION

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.

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, renal or 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 events. 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 [Package Insert]. Nashville, TN: Cumberland Pharmaceuticals Inc. 2019

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

CUMBERLAND® PHARMACEUTICALS