

CHILDRENS MOTRIN- ibuprofen suspension
Johnson & Johnson Consumer Inc.

Children's Motrin

Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen 100 mg (NSAID) ¹

¹ nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

temporarily:

- relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache
- reduces fever

Warnings

Allergy alert

Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if your child:

- has had stomach ulcers or bleeding problems
- takes a blood thinning (anticoagulant) or steroid drug
- takes other drugs containing prescription or nonprescription NSAIDs (aspirin,

ibuprofen, naproxen, or others)

- takes more or for a longer time than directed

Heart attack and stroke warning

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Sore throat warning

Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.

Do not use

- if the child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to your child
- child has a history of stomach problems, such as heartburn
- child has problems or serious side effects from taking pain relievers or fever reducers
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
- child has high blood pressure, heart disease, liver cirrhosis, kidney disease, or had a stroke
- child has asthma
- child is taking a diuretic

Ask a doctor or pharmacist before use if the child is

- under a doctor's care for any serious condition
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- child experiences any of the following signs of stomach bleeding:
 - feels faint
 - vomits blood
 - has bloody or black stools
 - has stomach pain that does not get better
- child has symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling

- the child does not get any relief within first day (24 hours) of treatment
- fever or pain gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- shake well before using
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed dosing cup. Do not use any other dosing device.
- if needed, repeat dose every **6-8 hours**
- do not use more than **4 times a day**
- replace original bottle cap to maintain child resistance

Dosing Chart

| Weight (lb) | Age (yr) | Dose (mL) * |
|--------------------|-----------------|--------------------|
| under 24 | under 2 years | ask a doctor |
| 24-35 lbs | 2-3 years | 5 mL |
| 36-47 lbs | 4-5 years | 7.5 mL |
| 48-59 lbs | 6-8 years | 10 mL |
| 60-71 lbs | 9-10 years | 12.5 mL |
| 72-95 lbs | 11 years | 15 mL |

* or as directed by a doctor

Other information

- **each 5 mL contains:** sodium 2 mg
- store between 20-25°C (68-77°F)
- **do not use if carton is opened or if carton tape or bottle wrap imprinted "SAFETY SEAL®" is broken or missing**

Inactive ingredients

acesulfame potassium, anhydrous citric acid, D&C red no. 33, FD&C blue no.1, FD&C red no. 40, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum

Questions or comments?

Call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

See New Warnings

NDC 50580-603-04

For Ages 2 to 11 Years

***Children's
Motrin[®]***

*contains **Ibuprofen**
Oral Suspension (NSAID)
100 mg per 5 mL*

Pain Reliever / Fever Reducer

***Lasts up to
8 hours***

Alcohol Free

Grape Flavor

4 fl oz (120 mL)



CHILDRENS MOTRIN

ibuprofen suspension

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50580-603 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 100 mg in 5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| WATER (UNII: 059QF0K00R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SUCROSE (UNII: C151H8M554) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | purple | Score | |
| Shape | | Size | |
| Flavor | GRAPE | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:50580-603-04 | 1 in 1 CARTON | 01/25/2016 | |
| 1 | | 120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| NDA | NDA020516 | 01/25/2016 | |

Labeler - Johnson & Johnson Consumer Inc. (878046358)