Children's Motrin

Drug Facts

Active ingredient (in each 5 mL)
Ibuprofen 100 mg (NSAID)\textsuperscript{1}

\textsuperscript{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

<table>
<thead>
<tr>
<th>Weight (lb)</th>
<th>Age (yr)</th>
<th>Dose (mL)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>under 24</td>
<td>under 2 years</td>
<td>ask a doctor</td>
</tr>
<tr>
<td>24-35 lbs</td>
<td>2-3 years</td>
<td>5 mL</td>
</tr>
<tr>
<td>36-47 lbs</td>
<td>4-5 years</td>
<td>7.5 mL</td>
</tr>
<tr>
<td>48-59 lbs</td>
<td>6-8 years</td>
<td>10 mL</td>
</tr>
<tr>
<td>60-71 lbs</td>
<td>9-10 years</td>
<td>12.5 mL</td>
</tr>
<tr>
<td>72-95 lbs</td>
<td>11 years</td>
<td>15 mL</td>
</tr>
</tbody>
</table>

* 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, 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 50580-184-50
For Ages 2 to 11 Years
Children’s Motrin®
contains Ibuprofen
Oral Suspension (NSAID)
100 mg per 5 mL
Pain Reliever / Fever Reducer
DYE - FREE
Lasts up to
8 hours
Alcohol Free
Non-Staining
Original Berry Flavor
4 fl oz (120 mL)
CHILDRENS MOTRIN
ibuprofen suspension

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
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Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
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www.motrin.com 30038105
### Product Information

<table>
<thead>
<tr>
<th><strong>Product Type</strong></th>
<th><strong>Item Code (Source)</strong></th>
<th>NDC:50580-184</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route of Administration</td>
<td></td>
<td>ORAL</td>
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### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th><strong>Ingredient Name</strong></th>
<th><strong>Basis of Strength</strong></th>
<th><strong>Strength</strong></th>
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</thead>
<tbody>
<tr>
<td>Ibuprofen (UNII: WK2XYI10QM) (Ibuprofen - UNII:WK2XYI10QM)</td>
<td>Ibuprofen</td>
<td>100 mg in 5 mL</td>
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### Inactive Ingredients

<table>
<thead>
<tr>
<th><strong>Ingredient Name</strong></th>
<th><strong>Strength</strong></th>
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</thead>
<tbody>
<tr>
<td>acesulfame potassium (UNII: 23OV73Q5G9)</td>
<td></td>
</tr>
<tr>
<td>anhydrous citric acid (UNII: XF417D3PSL)</td>
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</tr>
<tr>
<td>glycerin (UNII: PDC6A3C0OX)</td>
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<tr>
<td>polysorbate 80 (UNII: 6OZP39ZG8H)</td>
<td></td>
</tr>
<tr>
<td>water (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>sodium benzoate (UNII: OJ245FE5EU)</td>
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<tr>
<td>sucrose (UNII: C151H8M554)</td>
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<tr>
<td>xanthan gum (UNII: TTV12P4NEE)</td>
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### Product Characteristics

<table>
<thead>
<tr>
<th><strong>Color</strong></th>
<th><strong>Score</strong></th>
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<tbody>
<tr>
<td>WHITE (Off-white)</td>
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</tr>
<tr>
<td><strong>Shape</strong></td>
<td><strong>Size</strong></td>
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<tr>
<td></td>
<td></td>
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<tr>
<td><strong>Flavor</strong></td>
<td><strong>Imprint Code</strong></td>
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<tr>
<td>BERRY</td>
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### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th><strong>Item Code</strong></th>
<th><strong>Package Description</strong></th>
<th><strong>Marketing Start Date</strong></th>
<th><strong>Marketing End Date</strong></th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:50580-184-50</td>
<td>1 in 1 CARTON</td>
<td>02/28/2012</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>NDC:50580-184-51</td>
<td>2 in 1 PACKAGE</td>
<td>02/04/2019</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>1 in 1 CARTON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>120 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

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<thead>
<tr>
<th><strong>Marketing Category</strong></th>
<th><strong>Application Number or Monograph Citation</strong></th>
<th><strong>Marketing Start Date</strong></th>
<th><strong>Marketing End Date</strong></th>
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<tr>
<td>NDA</td>
<td>NDA020516</td>
<td>09/01/2001</td>
<td></td>
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