

## **IBUPROFEN CHILDRENS - ibuprofen suspension**

### **Major Pharmaceuticals**

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### **Major Pharmaceuticals Children's Ibuprofen Oral Suspension Drug Facts**

#### **Active ingredient (in each 5 mL)**

Ibuprofen 100 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

#### **Purposes**

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**

- give 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
- wash dosage cup after each use

### Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)**
under 24 lbs	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
- **do not use if printed neckband is broken or missing**
- store at 20-25°C (68-77°F)
- do not freeze

### Inactive ingredients

anhydrous citric acid, D&C red #33, FD&C blue #1, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, natural and artificial grape flavor, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

### Questions or comments?

**1-800-719-9260**

**Principal Display Panel**

MAJOR<sup>®</sup>

compare to the active ingredient of Children's Motrin<sup>®</sup>

children's ibuprofen oral suspension

ibuprofen oral suspension 100 mg per 5 ml

pain reliever/fever reducer (NSAID)

lasts up to 8 hours

relief for minor aches and pains

ages 2 to 11 years

alcohol free

paraben free

gluten free

4 fl oz (120 mL)

grape flavor

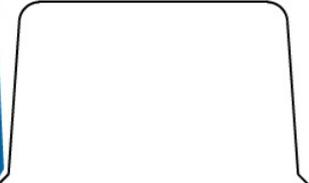
dosage cup included



**MAJOR**® NDC 0904-5577-20

**children's  
ibuprofen  
oral suspension**

ibuprofen oral suspension  
100 mg per 5 mL  
pain reliever/fever reducer (NSAID)



**Drug Facts (continued)**

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**Questions or comments?**  
1-800-719-9260

\*\*\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Children's Motrin®.

Distributed by:  
**MAJOR® PHARMACEUTICALS**  
Indianapolis, IN 46268  
(800) 616-2471 www.major-rugby.com

**DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING**

**KEEP CARTON FOR REFERENCE**

**MAJOR**® NDC 0904-5577-20  
compare to the active ingredient in Children's Motrin\*\*\*

**children's  
ibuprofen  
oral suspension**

**ibuprofen  
oral suspension  
100 mg per 5 mL**

pain reliever/fever reducer (NSAID)

lasts up to 8 hours  
relief for minor aches  
and pains  
ages 2 to 11 years

alcohol free  
paraben free  
gluten free



**4 fl oz (120 mL)** grape flavor  
dosage cup included

**Important: Read all product information before using. Keep this box for important information. This product is intended for use in children.**

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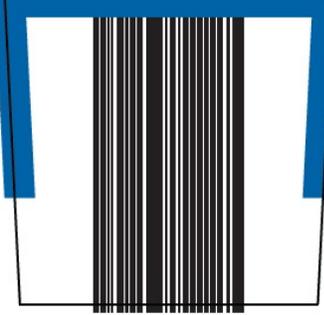
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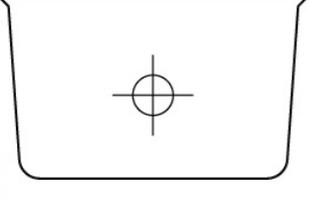
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Rev. 04/25 M-05 Re-order No. 005879

66026 5C C11



**IBUPROFEN CHILDRENS**  
ibuprofen suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-5577
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA05BB0L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

**Product Characteristics**

<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5577-20	1 in 1 CARTON	04/03/2002	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074937	04/03/2002	

**Labeler** - Major Pharmaceuticals (191427277)