

**CHILDRENS IBUPROFEN ORAL SUSPENSION- ibuprofen suspension**  
**Marc Glassman, Inc.**

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**Children's Ibuprofen Oral Suspension**

***Drug Facts***

***Active ingredient***

***(in each 5 mL)***

Ibuprofen 100 mg

***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

## DosingChart

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
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 printed bottle neckband is broken or missing**
- see bottom panel for lot number and expiration date

### **Inactive ingredients**

Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

## **Product Label**

**MARC'S®**

**Children's  
Ibuprofen**

**Pain Reliever/Fever Reducer**

**NDC 68998-320-24**

compare to the active ingredient  
in children's Motrin ®\*\*

**MARC'S ®**

**SEE NEW WARNINGS**

**Children's  
Ibuprofen  
Oral Suspension (NSAID)  
100 mg per 5 mL**

Pain Reliever/Fever Reducer

- **Alcohol-Free**
- **Lasts up to 8 Hours**
- **For Ages 2 to 11 Years**

**Original Berry Flavor**

4 FL OZ (118 mL)

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

\*\*This product is not manufactured or distributed by McNeil  
Consumer Healthcare, distributor of Children's Motrin<sup>®</sup>

**Distributed by:** Marc Glassman, Inc.                      **BX-091**  
West 1301h street  
Cleveland, OH 44130

**Bottle Label**

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

NDC 68998-320-24

**Marc's**

**Drug Facts**  
**Active ingredient**  
**in each 5 mL**

Ibuprofen 100 mg (NSAID)\*..... Pain reliever/  
fever reducer

\*nonsteroidal anti-inflammatory drug

**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

**Purpose**

**Children's**  
**Ibuprofen**

Oral Suspension (NSAID) 100 mg per 5 mL

**Pain Reliever/Fever Reducer**

**Original Berry Flavor**

4 FL OZ  
(118 mL)

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



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PEEL HERE

**Drug Facts (continued)**

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 below. 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**

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\*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 printed neckband is broken or missing**

**Inactive ingredients** Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose and xanthan gum

**Questions or comments:** Call weekdays from 9:30 AM to 4:30 PM EST at **1-877-798-5944.**

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

**Distributed by:**  
Marc Glassman, Inc.  
West 130th street  
Cleveland, OH 44130

**Carton Label**



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## CHILDRENS IBUPROFEN ORAL SUSPENSION

ibuprofen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68998-320
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	100 mg in 5 mL	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
GLYCERIN (UNII: PDC6A3C0OX)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCROSE (UNII: C151H8M554)				
XANTHAN GUM (UNII: TTV12P4NEE)				
<b>Product Characteristics</b>				
Color	orange	Score		
Shape		Size		
Flavor	BERRY	Imprint Code		
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68998-320-24	1 in 1 PACKAGE	03/09/2020	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA210602	03/09/2020		

**Labeler** - Marc Glassman, Inc. (094487477)