

IBUPROFEN CHILDRENS- ibuprofen suspension

HyVee Inc

Hy-Vee, Inc. Children's Ibuprofen Oral Suspension Drug Facts

Active ingredient (in each 5 mL = 1 teaspoonful)

Ibuprofen 100 mg (NSAID)*

*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

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 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, or kidney disease
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- 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
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed measuring cup
- 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 (lbs)	Age (yrs)	Dose (teaspoonful or mL)
under 2 years		ask a doctor
24-35 lbs	2-3 years	1 tsp or 5 mL
36-47 lbs	4-5 years	1 ½ tsp or 7.5 mL
48-59 lbs	6-8 years	2 tsp or 10 mL
60-71 lbs	9-10 years	2 ½ tsp or 12.5 mL
72-95 lbs	11 years	3 tsp or 15 mL

Other information

- each teaspoon 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
- see bottom panel for lot number and expiration date

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

Compare to Children's Motrin® Grape Flavor active ingredient

For Ages 2 to 11

Children's

Ibuprofen Oral Suspension

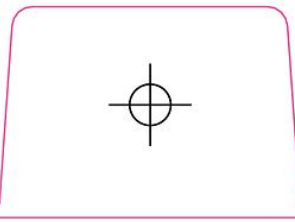
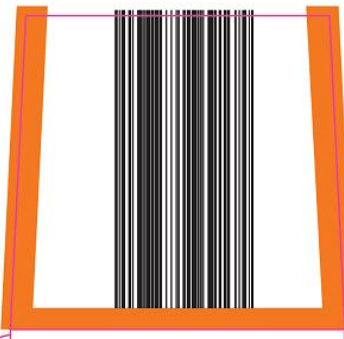
100 mg per 5 mL (teaspoonful)

Pain Reliever/Fever Reducer (NSAID)

Lasts up to 8 Hours

Grape Flavor

ALCOHOL FREE



Drug Facts (continued)

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Drug Facts (continued)

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Questions or comments?
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**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin® Grape Flavor.



DISTRIBUTED BY HY-VEE, INC.
5820 WESTOWN PARKWAY
WEST DES MOINES, IA 50266

SATISFACTION GUARANTEED
OR PURCHASE PRICE REFUNDED
FOR INFORMATION CALL 1-800-289-8343
www.hy-vee.com

KEEP CARTON FOR REFERENCE

NDC 42507-660-26

Compare to Children's Motrin® Grape Flavor active ingredient**

HyVee®
For Ages 2 to 11
Children's Ibuprofen
Oral Suspension
100 mg per 5 mL (teaspoonful)
Pain Reliever/Fever Reducer (NSAID)

HyVee®
For Ages 2 to 11
Children's Ibuprofen
Oral Suspension
100 mg per 5 mL (teaspoonful)
Pain Reliever/Fever Reducer (NSAID)

Lasts up to 8 Hours
Grape Flavor

ALCOHOL FREE
4 FL OZ (120 mL)

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

Drug Facts

Active ingredient	Purposes
(in each 5 mL = 1 teaspoonful) Ibuprofen 100 mg (NSAID)	Pain reliever/ fever reducer

*nonsteroidal anti-inflammatory drug

Uses temporarily:

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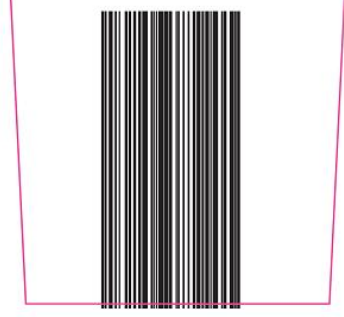
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0 75450 29264 0

LOT NO.

EXP.

: 66026 2H C7



IBUPROFEN CHILDRENS			
ibuprofen suspension			
Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:42507-660
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (IBUPROFEN)	IBUPROFEN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID	
D&C RED NO. 33	
FD&C BLUE NO. 1	
FD&C RED NO. 40	
GLYCERIN	
HIGH FRUCTOSE CORN SYRUP	
HYPROMELLOSES	
POLYSORBATE 80	
WATER	
SODIUM BENZOATE	
SORBITOL	
XANTHAN GUM	

Product Characteristics

Color	PURPLE (opaque)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-660-26	1 in 1 CARTON		
1		120 mL in 1 BOTTLE		
2	NDC:42507-660-28	1 in 1 CARTON		
2		148 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074937	04/01/2002	

Labeler - HyVee Inc (006925671)