

IBUPROFEN - ibuprofen suspension
H.J. Harkins Company, Inc.

Major Pharmaceuticals 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

- the 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 (lb)	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
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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)
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, artificial mixed berry flavor, D&C yellow #10, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments?

1-800-719-9260

Relabeled by:

H.J. Harkins Company, Inc.

Nipomo, CA 93444

Principal Display Panel

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

See New Warnings Information

Berry Flavored Liquid

Alcohol Free

Children's

COMPARE TO the active ingredient of CHILDREN'S MOTRIN®

52959-298-04

RX Only: #XXXXXXXX

#XXX

CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

IBUPROFEN 100mg/5ml CHILD SUSP

Lot #: IBF60M

Mfg: MAJOR

Exp: 09/09

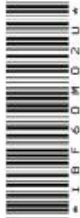
Mfg Livonia, MI

Loc.:

Compare to: Motrin-Berry FL

Mfg. NDC: 0904-5309-20

Pill ID: Liquid



Take as directed by your Doctor or
See outsert for usual dosage information



IBUPROFEN 100mg/5ml CHILD SUSP
52959-298-04 Qty 4oz
09/09 Lot IBF60M
Motrin-Berry FL 0904-5309-20

IBUPROFEN 100mg/5ml CHILD SUSP
52959-298-04 Qty 4oz
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IBUPROFEN 100mg/5ml CHILD SUSP
52959-298-04 Qty 4oz
09/09 Lot IBF60M
Motrin-Berry FL 0904-5309-20

Repack: HJ Harkins Co., Inc. Nipomo, CA 93444
Dispense in tight, child & light-resistant container per USP

Children's Ibuprofen Oral Suspension Carton Image 1**IBUPROFEN**

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52959-298(NDC:0904-5309)
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYL PARABEN (UNII: 3QP1I1U3FV8)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics				
Color	ORANGE	Score		
Shape		Size		
Flavor	BERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-298-04	1 in 1 CARTON		
1		240 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA074937	02/07/1999		

Labeler - H.J. Harkins Company, Inc. (147681894)

Registrant - H.J. Harkins Company, Inc. (147681894)

Establishment			
Name	Address	ID/FEI	Business Operations
H.J. Harkins Company, Inc.		147681894	repack, relabel