

PAIN AND FEVER- ibuprofen suspension

CVS PHARMACY, INC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen, USP 100 mg (NSAID)**

**Nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

temporarily

- relieves minor aches and pains due to: 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 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 drug containing prescription or nonprescription NSAIDs (aspirin,

ibuprofen naproxen, or others)

- takes more or for 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 a doctor.

Do not use

- if your child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after hear surgery

Ask a doctor before use if

- stomach bleeding warning applies to your child
- child has 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 your 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
 - vomit 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 (24hours) 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 (1-800-222-1222) right away.

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 the 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

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2	ask a doctor
24-35	2-3	5 mL
36-47	4-5	7.5 ml
48-59	6-8	10 mL
60-71	9-10	12.5 mL
72-95	11	15 mL

*or as directed by a doctor

Other information

- **each 5 mL contains:** sodium 2 mg
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

acesulfame potassium, artificial grape flavor, citric acid anhydrous, FD&C red #33, FD&C blue #1, FD&C red #40, glycerin, polysorbate 80, pregelatinized corn starch, purified water, sodium benzoate, sucrose, xanthan gum

Questions or Comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredients in Children's Motrin®†

For ages 2 to 11

Children's

Ibuprofen

Oral Suspension

100 mg per 5 mL

Pain reliever;

Fever reducer NSAID

No added alcohol

LAST UP TO 8 HOURS

Grape Flavor

Dosage Cup Included

FL OZ (mL)

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

TAMPER EVIDENT: DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING.

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive

Woonsocket, RI 02895

Product Label

Drug Facts (continued)

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- stomach bleeding warning applies to your child
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Distributed by:
CVS Pharmacy, Inc.
One CVS Drive
Woonsocket, RI 02895
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1-800-SHOP CVS
V-19654

100% money back guaranteed.
CVS.com/returnpolicy

CVS Health.

Compare to the active ingredient in Children's Motrin®
Oral Suspension
NDC 51316-938-04

For ages 2 to 11 Children's

Ibuprofen

Oral Suspension
100 mg per 5 mL

Pain reliever; Fever reducer (NSAID)
No added alcohol





Grape Flavor
Dosage Cup Included

4 FL OZ (118 mL)

Package Contains One Bottle

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 (in each 5 mL)	Purpose
Ibuprofen, USP 100 mg (NSAID)**	Pain reliever/fever reducer
**nonsteroidal anti-inflammatory drug	

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Do not use

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- right before or after heart surgery

CVS HEALTH Ibuprofen 100 mg

PAIN AND FEVER

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-938
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-938-04	1 in 1 BOX	02/15/2023	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/15/2023	

Labeler - CVS PHARMACY, INC (062312574)

Revised: 3/2023

CVS PHARMACY, INC