

CHILDRENS ADVIL- ibuprofen suspension
Haleon US Holdings LLC

Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Fever reducer/Pain reliever

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

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 the 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 any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to the child
- child has problems or serious side effects from taking pain relievers or fever reducers
- child has a history of stomach problems, such as heartburn
- child has high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
- 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.

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.
- repeat dose every **6-8 hours**, if needed
- do not use more than **4 times a day**
- measure only with the dosing cup provided. Dosing cup to be used with Children's Advil Suspension only. Do not use with other products. Dose lines account for product remaining in cup due to thickness of suspension.

Dosing Chart

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

Other information

- each 5 mL contains: **sodium 10 mg**
- one dose lasts 6-8 hours
- store at 20-25°C (68-77°F)
- see bottom of box for lot number and expiration date

Inactive ingredients

artificial and natural flavors, carboxymethylcellulose sodium, citric acid monohydrate,

edetate disodium, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucrose, xanthan gum

Questions or comments?

call toll-free **1-800-88-ADVIL** or ask your pharmacist, doctor or health care professional

Additional Information

Long Lasting: Up to 8 hours of fever reduction

Great Convenience: Long duration means fewer doses needed per day.

Alcohol-Free

For most recent production information,

Visit www.Advil.com

Pfizer, Madison, NJ 07940 USA © 2019 Pfizer Inc.

Important: Read all product information before using. Keep this box for important information. This product is intended for use in children ages 2 years - 11 years.

Packaged with Tamper-Evident bottle cap.

Do Not Use if breakable ring is separated or missing.

PRINCIPAL DISPLAY PANEL

NDC0573-1174-12

**Children's
Advil®**

Suspension

Ibuprofen Oral Suspension

100 mg per 5 mL

Pain Reliever/Fever Reducer (NSAID)

Fever

Aches & Pains

Lasts Up To

8

Hours

Same Great Flavor!

Now Dye-Free

Dye-Free

BLUE RASPBERRY

**Blue Raspberry-Flavored Liquid
for ages 2-11 years**

4 FL OZ (120 mL)

Alcohol-Free

PAA105480 Front Carton

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CHILDRENS ADVIL

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-1174
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
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (Translucent)	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-1174-12	1 in 1 CARTON	09/30/2019	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020589	06/27/1996	

