

CHILDRENS IBUPROFEN - ibuprofen suspension
Aurohealth LLC

Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen USP 100 mg (NSAID)*

Purpose

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 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 to 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 (year)	Dose (mL)*
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 to 25°C (68 to 77°F)
- **do not use if carton is opened or seal under cap opening is broken or missing**
- see bottom panel for lot number and expiration date

Inactive ingredients

Acesulfame potassium, art grape flavor, citric acid anhydrous, D&C Red No. 33, FD&C blue No. 1, FD&C red No. 40, glycerin, hypromellose, polysorbate 80, pregelatinized starch (potato), propylene glycol, purified water, sodium benzoate,

sucrose and xanthan gum

Questions or comments?

Call **1-855-274-4122**

Distributed by:

AUROHEALTH LLC

2572 Brunswick Pike

Lawrenceville, NJ 08648

Made in India

Code: TS/DRUGS/19/1993

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 4 FL OZ (120 mL) Container Label

NDC 58602-003-24

For Ages 2 to 11 Years

Children's

Ibuprofen

Oral Suspension USP

100 mg per 5 mL

Pain Reliever/Fever Reducer (NSAID)

Lasts up to

8 hours

Alcohol Free

Grape Flavor

4 FL OZ (120 mL)

AUROHEALTH

Ingredient Name		Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	100 mg in 5 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
GRAPE (UNII: 6X543N684K)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYPROMELLOSE 2208 (4000 MPA.S) (UNII: 39J80LT57T)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
STARCH, POTATO (UNII: 8I089SAH3T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCROSE (UNII: C151H8M554)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color	PURPLE (Light purple to purple)	Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-003-24	1 in 1 CARTON	06/16/2021	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:58602-003-20	1 in 1 CARTON	06/16/2021	
2		240 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	
ANDA	ANDA209179	06/16/2021		

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(58602-003) , MANUFACTURE(58602-003)

Revised: 6/2021

Aurohealth LLC