

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 raspberry flavor, citric acid anhydrous, D&C yellow No. 10, FD&C red No. 40, glycerin, hypromellose, polysorbate 80, pregelatinized starch (potato), 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 58602-200-24

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
Berry Flavor
4 FL OZ (120 mL)
AUROHEALTH

Top Ply

<p>NDC 58602-200-24</p> <p>For Ages 2 to 11 Years</p> <p>Children's</p> <p>Ibuprofen Oral Suspension USP 100 mg per 5 mL</p> <p><i>Pain Reliever/Fever Reducer (NSAID)</i></p> <p>Alcohol Free Berry Flavor</p> <p>Lasts up to 8 hours</p> <p>4 FL OZ (120 mL)</p> <p>AUROHEALTH</p>	<p>Important: Read all product information before using. Keep this box for important information. This product is intended for use in children.</p>	<p>Lift Here for Drug Facts</p>																	
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Back of Top Ply (Page #2)

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Base (Page #3)

Drug Facts (continued)**Directions**

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Drug Facts (continued)**Other information**

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 ■ store between 20 to 25°C (68 to 77°F)
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Inactive ingredients

Acesulfame potassium, art raspberry flavor, citric acid anhydrous, D&C yellow No. 10, FD&C red No. 40, glycerin, hypromellose, polysorbate 80, pregelatinized starch (potato), purified water, sodium benzoate, sucrose and xanthan gum

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Code: TS/DRUGS/19/1993

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 4 FL OZ (120 mL) Carton Label**NDC 58602-200-24****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****Berry Flavor****4 FL OZ (120 mL)****AUROHEALTH**

KEEP IN OUTER CARTON UNTIL CONTENTS USED

Drug Facts (continued)

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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

Lot

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LEBG730X

CHILDRENS IBUPROFEN			
ibuprofen suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-200
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
RASPBERRY (UNII: 4N14V5R27W)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
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)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	ORANGE (Light orange to orange)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-200-24	1 in 1 CARTON	04/17/2018	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:58602-200-20	1 in 1 CARTON	04/17/2018	
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	04/17/2018	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(58602-200) , MANUFACTURE(58602-200)

Revised: 12/2019

Aurohealth LLC