

CHILDRENS IBUPROFEN- ibuprofen suspension
BluePoint Laboratories

Ibuprofen Oral Suspension USP Rev 0420

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**

Manufactured by:

**Aurobindo Pharma Limited
Hyderabad - 500 090, India
For BluePoint Laboratories**

Made in India

Code: TS/DRUGS/19/1993

Issued: 04/2020

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

NDC 68001-435-92

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)

BluePoint Laboratories

NDC 68001-435-92
For Ages 2 to 11 Years
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Ibuprofen
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**Pain Reliever/
Fever Reducer (NSAID)**
Alcohol Free • Lasts up to 8 Hours

Berry Flavor

BluePoint
LABORATORIES 4 FL OZ (120 mL)

Important: Read all product information before using. Keep the box for important information. This product is intended for use in children.

Purpose
Ibuprofen USP 100 mg (NSAID)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 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 warnings: 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 disease, 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 or symptoms: ■ 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 below. 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 dosing cup after each use

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72-85 lbs	11 years	15 mL

* or as directed by a doctor
Issued: 04/2020

Other information ■ each 5 mL contains: sodium 2 mg ■ store between 20 to 25°C (68 to 77°F) ■ do not use if seal under cap is broken or missing
Inactive ingredients: Acesulfame potassium, artificial 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

Manufactured by:
Aurobindo Pharma Limited
Hyderabad-500 090, India
For BluePoint Laboratories
Made in India
Code: TS/DRUGS/191983

LM-4115

P 14 2 6 1 6 2

LOT
EXP

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

NDC 68001-435-92

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)

BluePoint Laboratories

NDC 68001-435-92

For Ages 2 to 11 Years Children's

Ibuprofen

Oral Suspension USP

Pain Reliever/
Fever Reducer (NSAID)

LM-4116
P1040866

Unvarnished Zone
(dotted line not for printing)

Unvarnished Zone
(dotted line not for printing)

KEEP IN OUTER CARTON UNTIL CONTENTS USED

Drug Facts (continued)

wash dosage cup after each use

Dosing Chart

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Manufactured by:
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Hyderabad-500 060, India
For BluePoint Laboratories

Made in India

Code: TS/DRUGS/19/1993

Issued: 04/2020

NDC 68001-435-92

For Ages 2 to 11 Years Children's

Ibuprofen

Oral Suspension USP

100 mg per 5 mL

**Pain Reliever/
Fever Reducer (NSAID)**

Alcohol Free • Lasts up to 8 Hours

Use ONLY enclosed dosage cup

BluePoint LABORATORIES 4 FL OZ (120 mL)

LOT: _____

EXP: _____

Unvarnished Zone
(dotted line not for printing)

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Drug Facts

Active ingredient (in each 5 mL) **Purpose**

Ibuprofen USP 100 mg (NSAID)*.....Pain reliever/
fever reducer

* nonsteroidal anti-inflammatory drug

Uses

temporarily:

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Do not use

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- 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

Drug Facts (continued)

- child has problems or serious side effects from taking pain relievers or fever reducers
- child has not been drinking fluids
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- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance

Artwork Colors

 YELLOW	 P 3275 C
 BLACK	 P BLUE 072 C
 MAGENTA	 P 383 C
 CYAN	 P 549 C

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Subhe
Body t
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CHILDRENS IBUPROFEN

ibuprofen suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68001-435

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:68001-435-92	1 in 1 CARTON	06/18/2020	03/31/2025
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:68001-435-94	1 in 1 CARTON	06/18/2020	05/31/2024
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	06/18/2020	03/31/2025

Labeler - BluePoint Laboratories (985523874)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	analysis(68001-435) , manufacture(68001-435)

Revised: 5/2023

BluePoint Laboratories