### CHILDRENS IBUPROFEN- ibuprofen suspension BluePoint Laboratories

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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)

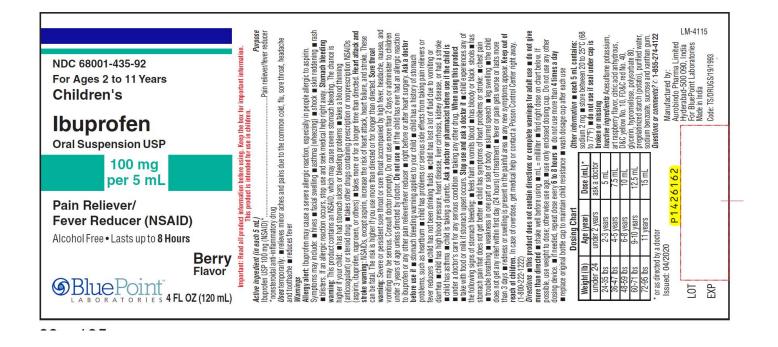
Lasts up to

8 hours

Alcohol Free

# 4 FL OZ (120 mL)

## **BluePoint Laboratories**



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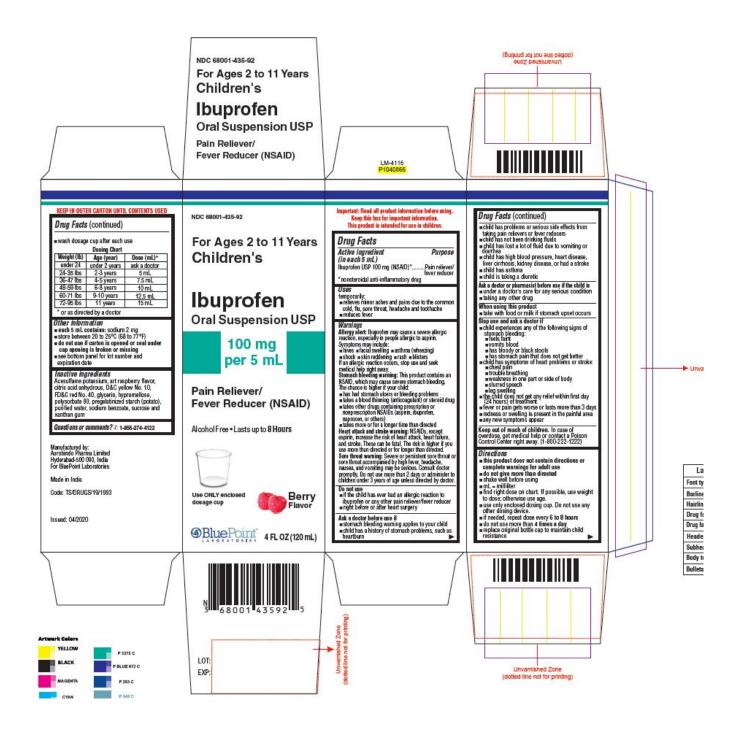
8 hours

**Alcohol Free** 

**Berry Flavor** 

# 4 FL OZ (120 mL)

### **BluePoint Laboratories**



# CHILDRENS IBUPROFEN ibuprofen suspension Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68001-435

Active migree	lient/Active Moiety					
	Ingredient Name	Basi	s of Strength	Strength		
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)			FEN	100 mg in 5 mL		
Inactive Ingr				Strength		
	Ingredient Name					
	TASSIUM (UNII: 230V73Q5G9)					
	RIC ACID (UNII: XF417D3PSL) <b>10</b> (UNII: 35SW5USQ3G)					
FD&C RED NO. 40 (UNII: WZ B9127XOA)           GLYCERIN (UNII: PDC6A3C0OX)						
•	2208 (4000 MPA.S) (UNII: 39/80LT57T)					
POLYSORBATE 80 (UNII: 60ZP39ZG8H)						
	(UNII: 810895AH3T)					
WATER (UNII: 059QF0K00R)						
ODIUM BENZOA	TE (UNII: OJ245FE5EU)					
SUCROSE (UNII: C	151H8M554)					
KANTHAN GUM (L	INII: TTV12P4NEE)					
Color	orange (Light orange to orange) Score					
Shape Flavor	Size					
Contains	BERRY		Imprint Code			
contains						
Packaging						
5 5		Marke	ting Start	Markating End		
	Package Description		Date	Date		
# Item Code	Package Description	06/18/20				
<ul> <li># Item Code</li> <li>NDC:68001- 435-92</li> </ul>				Date		
<ul> <li># Item Code</li> <li>NDC:68001- 435-92</li> <li>NDC:68001</li> </ul>	1 in 1 CARTON 120 mL in 1 BOTTLE; Type 1: Convenience Kit of		20 0	Date		
<ul> <li># Item Code</li> <li>NDC:68001- 435-92</li> <li>NDC:68001- 435-94</li> </ul>	1 in 1 CARTON 120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	06/18/20	20 0	93/31/2025		
<ul> <li># Item Code</li> <li>NDC:68001- 435-92</li> <li>NDC:68001- 435-94</li> </ul>	1 in 1 CARTON 120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package 1 in 1 CARTON 240 mL in 1 BOTTLE; Type 1: Convenience Kit of	06/18/20	20 0	<b>Date</b> 03/31/2025		
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# Labeler - BluePoint Laboratories (985523874)

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

Revised: 5/2023

**BluePoint Laboratories**