

**CHILDRENS IBUPROFEN - ibuprofen suspension**  
**Randob Labs., Ltd.**

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**CHILDREN'S IBUPROFEN**

***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**

<b>Weight (lb)</b>	<b>Age (year)</b>	<b>Dose (mL)*</b>
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, citric acid anhydrous, D&C yellow No. 10, FD&C red No. 40, glycerin, hypromellose, N&A flavor for cherry blast, N&A strawberry flavor wild, polysorbate 80, pregelatinized starch (potato), propylene glycol, purified water, sodium benzoate, sucrose and xanthan gum

***Questions or comments?***

Call **1-833-389-9450**

Distributed by  
CrossingWell Consumer Health  
PO Box 440  
Cornwall, NY 12518

Made in India

Code: TS/DRUGS/19/1993

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

**For Ages 2 to 11 Years**

***Pedia  
Care®  
100% dedicated  
to kids™***

**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)**

**Berry Flavor**

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) **Berry Flavor**

**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

**Active Ingredient (in each 5 mL)**  
Ibuprofen USP 100 mg (NSAID)\*.....Pain reliever/fever reducer

**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 redness; rash. 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 you take: aspirin or other drugs containing aspirin; other pain relievers; blood thinning medicine; or steroid drugs. Other conditions that increase the risk of stomach bleeding include: heart disease; liver or kidney disease; stomach ulcers; or a history of stomach ulcers. **Stroke warning:** NSAIDs, especially aspirin, increase the risk of heart attack, heart failure, and stroke. The risk is higher if you use more than directed or for longer than directed. **Severe throat warning:** Severe or persistent sore throat or sore throat accompanied by high fever, headache, voice, 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: red stools; 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's swelling; the child does not get any relief within first 24 hours of treatment; fever or pain gets worse or lasts more than 3 days; or signs of dehydration: persistent dry mouth; dry skin; sunken eyes; sleepiness; and/or rash 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; ml (mL) 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's resistance; wash dosing cup after each use.

**Dosing Chart**

Weight (lb)	Age (year)	Dose (mL)*
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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 seal under cap is broken or missing. **Contains/ingredients:** ibuprofen, potassium chloride, polyethylene glycol, polyethylene glycol 400, polyethylene glycol 150, polyethylene glycol 200, polyethylene glycol 300, polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 800, polyethylene glycol 1000, polyethylene glycol 1500, polyethylene glycol 2000, polyethylene glycol 3000, polyethylene glycol 4000, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 10000, polyethylene glycol 15000, polyethylene glycol 20000, polyethylene glycol 30000, polyethylene glycol 40000, polyethylene glycol 60000, polyethylene glycol 80000, polyethylene glycol 100000. **Flavor:** Berry. **Other ingredients:** polyethylene glycol, purified water, sodium benzoate, sucrose, and artificial flavors. (1-800-369-9450)

Made in India Code: TS/DRUGS/19/1933

Distributed by  
CrossingWell Consumer Health  
PO Box 440, Cornwall, NY 12518

LOT: P1432643 LM-5278  
EXP:

CROSSINGWELL  
consumer health

Unvarnished Zone  
(dotted line not for printing)

LOT XXXXXXXXXX  
EXP MM/YYYY  
pre-printed batch details  
should be verified online  
during packing.

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

**Pedia  
Care®**  
**100% dedicated  
to kids™**  
**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)**



## Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
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)	
CHERRY (UNII: BUC5I9595W)	
STRAWBERRY (UNII: 4J2TY8Y81V)	
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	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:52412-911-04	1 in 1 CARTON	07/15/2023	
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
ANDA	ANDA209179	07/15/2023	

**Labeler** - Randob Labs., Ltd. (061995007)

**Registrant** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
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Aurobindo Pharma Limited		918917642	ANALYSIS(52412-911) , MANUFACTURE(52412-911)
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## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(52412-911) , MANUFACTURE(52412-911)

Revised: 9/2025

Randob Labs., Ltd.