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,

Questions or comments?

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

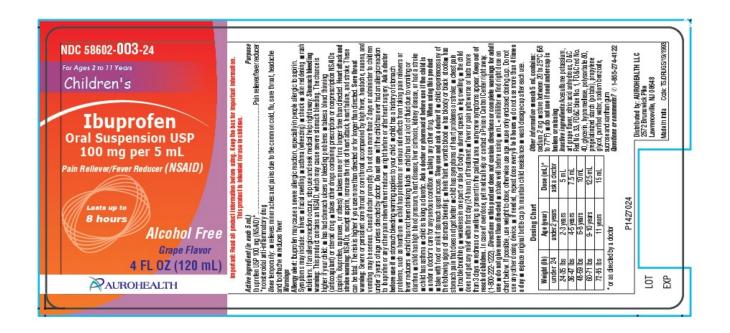
Distributed by: **AUROHEALTH LLC** 2572 Brunswick Pike Lawrenceville, NJ 08648

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

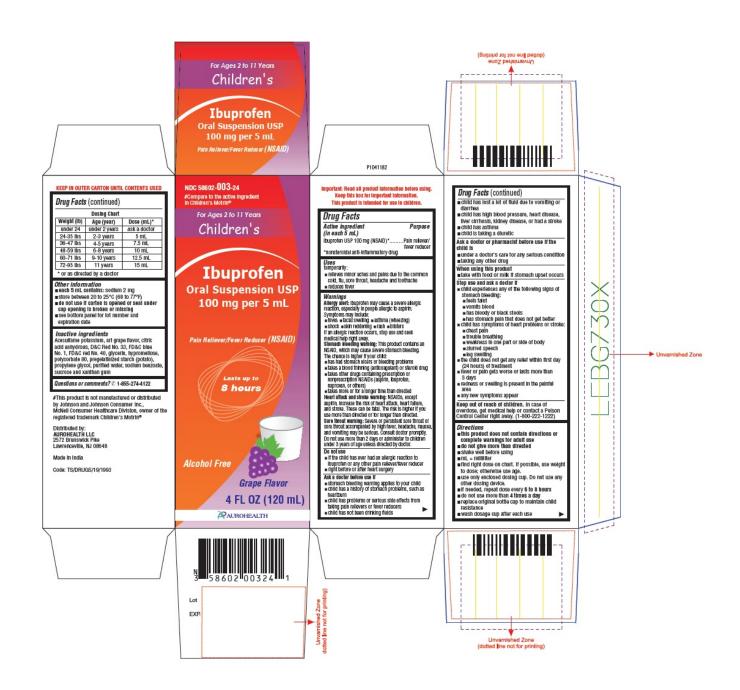


PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 4 FL OZ (120 mL) Carton Label

NDC 58602-003-24

4 FL OZ (120 mL) AUROHEALTH

#Compare to the active ingredient in Children's Motrin®
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



CHILDRENS IBUPROFEN

ibuprofen suspension

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58602-003 |
| 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: 230V73Q5G9) | | | | |
| 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: 60ZP39ZG8H) | | | | |
| STARCH, POTATO (UNII: 81089SAH3T) | | | | |
| 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 | | | |

| P | 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