

DYE FREE CHILDRENS IBUPROFEN- ibuprofen suspension
Precision Dose Inc.

DYE FREE CHILDREN'S IBUPROFEN ORAL SUSPENSION

Berry Flavor

100 mg/5 mL

For Hospital Use Only

Drug Facts

Active ingredient (in each 5 mL = 1 teaspoonful)

Ibuprofen 100 mg (NSAID)¹

¹ nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

temporarily:

- relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache
- reduces fever
- **Important: Read all product information before using.**
- **This product is intended for use in children.**

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

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 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, or kidney disease
- 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

- give with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- 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

- use as directed per healthcare professional
- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- shake well before using

- mL = milliliter; tsp = teaspoonful
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- if needed, repeat dose every **6-8 hours**
- do not use more than **4 times a day**

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL or tsp)*
under 24 lbs	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL (1 tsp)
36-47 lbs	4-5 years	7.5 mL (1½ tsp)
48-59 lbs	6-8 years	10 mL (2 tsp)
60-71 lbs	9-10 years	12.5 mL (2½ tsp)
72-95 lbs	11 years	15 mL (3 tsp)

* or as directed by a doctor

Other information

- **each 5 mL (1 tsp) contains:** sodium 2 mg
- store at 20-25°C (68-77°F)
- do not freeze
- see individual label or shipper for lot number and expiration date

Inactive ingredients

anhydrous citric acid, artificial mixed berry flavor, glycerin, high fructose corn syrup, hypromellose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Alcohol Free, Dye Free, Gluten Free

How Supplied

NDC 68094-600-61

5 mL per unit dose cup

One hundred (100) cups per shipper

NDC 68094-600-62

5 mL per unit dose cup

Thirty (30) cups per shipper

Distributed By

Perrigo Company

Allegan, MI 49010

Packaged By

Precision Dose, Inc.

South Beloit, IL 61080

LI 979 Rev. 03/17

PRINCIPAL DISPLAY PANEL - 100 mg/5 mL Cup Label

NDC 68094-600-59

PrecisionDose™

Children's IBUPROFEN

Oral Suspension

100 mg/5 mL

Pkg: Precision Dose, Inc., S. Beloit, IL 61080



DYE FREE CHILDRENS IBUPROFEN

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68094-600(NDC:0113-0685)
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
Anhydrous citric acid (UNII: XF417D3PSL)	
Glycerin (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
water (UNII: 059QF0K00R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
xanthan gum (UNII: TTV12P4NEE)	
high fructose corn syrup (UNII: XY6UN3QB6S)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68094-600-62	3 in 1 CASE	08/26/2015	
1		10 in 1 TRAY		
1	NDC:68094-600-59	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:68094-600-61	10 in 1 CASE	08/26/2015	
2		10 in 1 TRAY		
2	NDC:68094-600-59	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074937	08/26/2015	

