CHILDRENS IBUPROFEN- ibuprofen suspension
Cardinal Health

CHILDREN'S IBUPROFEN ORAL SUSPENSION

Berry Flavor

100 mg/5 mL 200 mg/10 mL

For Hospital Use Only

Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen 100 mg (NSAID)[1]

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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**
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- shake cups well before using
- mL = milliliter; tsp = teaspoonful
- 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, D&C yellow #10, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Alcohol Free, Gluten Free

How Supplied

Overbagged with 5 x 5 mL unit dose cups per bag, NDC 55154-1577-5

Distributed By
Perrigo Company
Allegan, MI 49010

Packaged By
Precision Dose, Inc.
South Beloit, IL 61080

Distributed By:
Cardinal Health

Dublin, OH 43017

LI587 Rev. 06/17

PRINCIPAL DISPLAY PANEL - 5 mL Cup Label

Children's IBUPROFEN Oral Suspension

100 mg/5 mL

5 Unit Dose Cups

NDC 55154-1577-5

Y62

CHILDREN'S IBUPROFEN ORAL SUSPENSION 100 mg/5 mL

5 UNIT DOSE CUPS

Delivers 5 mL

Each 5 mL contains: sodium 2 mg

Alcohol Free

Gluten Free

(NSAID)

Shake Well

See product insert for prescribing information, precautions and warnings.

STORAGE: Store at 20 - 25° C (68 - 77° F)
CAUTION: Do Not Expose To Heat
DO NOT FREEZE

WARNING: This Unit Dose package is not child resistant and is Intended for Hospital Use Only.
Keep this and all drugs out of the reach of children.

Pkg: Precision Dose, Inc.
South Beloit, IL 61080
PrecisionDose™

Distributed by Cardinal Health
Dublin, OH 43017
L37247700318

LOT #: XXXXXXXXXX EXP. DATE: XX/XX/XX

CHILDRENS IBUPROFEN

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55154-1577(NDC:68094-494)
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)	
butylparaben (UNII: 3QPI1U3FV8)	
corn syrup (UNII: 9G5L16BK6N)	
D&C red NO. 33 (UNII: 9DBA0SBB0L)	
FD&C yellow NO. 6 (UNII: H77VEI93A8)	
glycerin (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics			
Color	ORANGE	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55154-1577-5	5 in 1 BAG	04/13/2004	
1		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	04/13/2004	

Labeler - Cardinal Health (603638201)

Revised: 9/2018 Cardinal Health