LEADER CHILDRENS IBUPROFEN- ibuprofen suspension Cardinal Health 110, LLC. dba Leader

Cardinal Health Children's Ibuprofen Oral Suspension 100 mg per 5 mL Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen 100 mg (NSAID)*

*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

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 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

give 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 6-8 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 (yr)	Dose (mL)**	
under 24	under 2	ask a doctor	
lbs	years		
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
- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- do not freeze

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

Questions or comments?

1-800-719-9260

Principal Display Panel

SEE NEW WARNINGS

Children's Ibuprofen

Oral Suspension

100 mg per 5 mL

Pain Reliever / Fever Reducer

(NSAID)

Berry Flavor

For Ages 2 to 11 Years

COMPARE TO CHILDREN'S MOTRIN® active ingredient

Lasts up to 8 hours

Alcohol-Free

100% Money Back Guarantee

8 FL OZ (240mL)





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portaint. Read all product information before using. ep this box for important information. This product intended for use in children.

Drug Facts

Active ingredient (in each 5 mL)

Purposes

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Uses temporarily:

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Ask a doctor or pharmacist before use if the child is

■ under a doctor's care for any serious condition ■ taking any other drug

Drug Facts (continued)

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or as directed b	y a doctor	57	

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Inactive ingredients anhydrous citric acid, artificial mixed berry flavor, D&C yellow #10, FD&C red #40, glycerin, high fructoes corn syrup, hypromelbos, polyscrbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments? 1-800-719-9260

LEADER LEADER

Ibuprofen

***This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Motrin®.

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Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their

Oral Suspension

100 mg per 5 mL

Pain Reliever /

Fever Reducer

*CardinalHealth™

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

(NSAID)

Gluten Free

Children's

NDC 70000-0263-2

SEE NEW WARNINGS

Children's

Ibuprofen

Oral Suspension 100 mg per 5 mL

Pain Reliever / Fever Reducér (NSAID)

Berry Flavor

For Ages 2 to 11 Years Lasts up to

8 hours

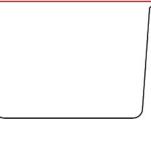
COMPARE TO CHILDREN'S MOTRIN® active ingredient***

100% Money Back Guarantee



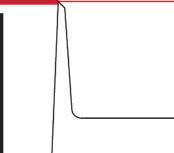
8 FL OZ (240mL)





All LEADER™ Brand Products Have A

100% Money Back Guarantee







89734 E9 C2

LEADER CHILDRENS IBUPROFEN

ibuprofen suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70000-0263

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)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
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			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0263-1	1 in 1 CARTON	03/28/2017	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000- 0263-2	1 in 1 CARTON	03/28/2017	
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:70000- 0263-3	1 in 1 CARTON	06/27/2017	
3		150 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	
Category	Citation	Date	Date	

ANDA ANDA074937 03/28/2017

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 6/2021 Cardinal Health 110, LLC. dba Leader