IBUPROFEN- ibuprofen suspension Kroger Company

Kroger Co. Children's Ibuprofen 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 lbs	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
- 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, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, natural and artificial bubblegum flavors, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments?

1-800-632-6900

Principal Display Panel

COMPARE TO the active ingredient of CHILDREN'S MOTRIN[®] See side panel OUR PHARMACIST RECOMMENDED Age 2 to 11 Years children's Ibuprofen Oral Suspension 100 mg per 5 mL Pain Reliever/Fever Reducer (NSAID) Alcohol Free Lasts up to 8 Hours Bubble Gum Flavor 4 FL OZ (118 mL)



BUPROFEN			
ouprofen suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-166
Route of Administration	ORAL		

Active Ingred	iont/Act	ive Moiety			
Active ingreu		•		Decis of Strengt	h Ctus nath
			Basis of Strengt		
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII: WK2XYI10QM)				IBUPROFEN	100 mg in 5 mL
Inactive Ingre	edients				
		Ingredient Name			Strength
ANHYDROUS CITE					
FD&C RED NO. 40 (UNII: WZ B9127XOA)					
GLYCERIN (UNII: P					
		UP (UNII: XY6UN3QB6S)			
		IED (UNII: 3NXW29V3WO)			
POLYSORBATE 80		ZP39ZG8H)			
WATER (UNII: 0590					
SODIUM BENZOA					
SORBITOL (UNII: 5		•			
XANTHAN GUM (U	NII: TTV12P	4NEE)			
Product Char	acterist				
Color	PINK (light) Sc			e	
Shape	Siz				
Flavor	BUBBLE GUM In		Impr	int Code	
Contains					
Packaging					
# Item Code		Package Description		Marketing Start Date	Marketing End Date
1 NDC:30142-166-	1 in 1 CARTON		1	1/20/2002	12/31/2023
1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product				
2 NDC:30142-166-	1 in 1 CARTON			3/28/2008	
- 34				5/20/2000	
2	240 mL in 1 BOTTLE; Type 0: Not a Combination Product				
3 NDC:30142-166-28	1 in 1 CARTON		0	9/04/2013	02/28/2021
3	147 mL in 1 BOTTLE; Type 0: Not a Combination Product		on		
		-			
Marketing	Inform	nation			
Marketing	Арр	lication Number or Monograp Citation	h	Marketing Start Date	Marketing End Date
Category		Citation			
Category ANDA	ANDA0			11/20/2002	

Labeler - Kroger Company (006999528)

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