IBUPROFEN- ibuprofen suspension
Kroger Company

Kroger Co. Children's Ibuprofen Oral Suspension Drug Facts

Active ingredient (in each 5 mL = 1 teaspoonful)

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

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

- 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.
- 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 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 (1 ½ tsp)
48-59 lbs	6-8 years	10 mL (2 tsp)
60-71 lbs	9-10 years	12.5 mL (2 ½ 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
- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- do not freeze
- see bottom panel for lot number and expiration date

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® BUBBLE GUM FLAVOR

See back panel

FOR AGES 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

8 FL OZ (240 mL)

COMPARE TO the active ingredient of CHILDREN'S MOTRIN® BUBBLE GUM FLAVOR ***See back panel

NDC 30142-166-34

FOR AGES 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

Our Pharmacists Recommend

Bubble Gum Flavor

8 FL OZ (240 mL)

COMPARE TO the active ingredient of CHILDREN'S MOTRIN® BUBBLE GUM FLAVOR ***See back panel

NDC 30142-166-34

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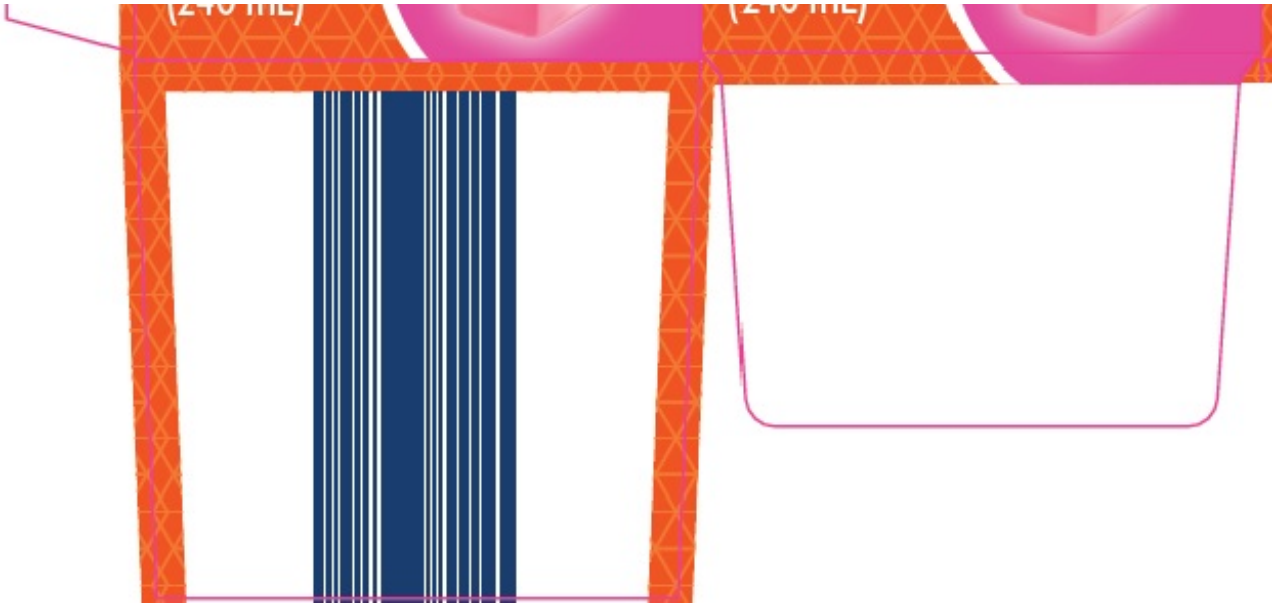

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OH 45202

QUALITY GUARANTEE GLUTEN FREE

www.kroger.com

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Kroger

FOR AGES 2 TO 11 YEARS

Children's Ibuprofen

Oral Suspension

100 mg per 5 mL

Pain Reliever/Fever Reducer (NSAID)

Important: Read all product information before using. Keep this box for important information. This product is intended for use in children.

Drug Facts

Active ingredient (in each 5 mL = 1 teaspoonful)	Purposes
Ibuprofen 100 mg (NSAID)*	Pain reliever/ fever reducer

*nonsteroidal anti-inflammatory drug

Uses temporarily:

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Drug Facts (continued)

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Questions or comments? 1-800-632-6900

IBUPROFEN

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30142-166
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PINK (light)	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-166-26	1 in 1 CARTON		
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:30142-166-34	1 in 1 CARTON		
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:30142-166-28	1 in 1 CARTON		
3		147 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074937	11/20/2002	

Labeler - Kroger Company (006999528)

Revised: 2/2016 Kroger Company