CHILDRENS IBUPROFEN- ibuprofen suspension
Safeway

Safeway Inc. Children's Ibuprofen Oral Suspension Drug Facts

Active ingredient (in each 5 mL = 1 teaspoonful)

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

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
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed measuring cup

- 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 (lbs)	Age(yrs)	Dose (teaspoonful or mL)
under 2 years		ask a doctor
24-35 lbs	2-3 years	1 tsp or 5 mL
36-47 lbs	4-5 years	1 ½ tsp or 7.5 mL
48-59 lbs	6-8 years	2 tsp or 10 mL
60-71 lbs	9-10 years	2 ½ tsp or 12.5 mL
72-95 lbs	11 years	3 tsp or 15 mL

Other information

- each teaspoon 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, D&C red #33, FD&C blue #1, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, natural and artificial grape flavor, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments?

1-888-SAFEWAY

Principal Display Panel

Compare to Children's Motrin® Grape Flavor active ingredient

Children's

For Ages 2 to 11

Ibuprofen Oral Suspension

100 mg per 5 mL (Teaspoonful)

Pain Reliever/Fever Reducer (NSAID)

Alcohol Free

Lasts Up to 8 Hours

Grape Flavored Liquid

Children's
For Ages 2 to 11

Ibuprofen
Oral Suspension

100 mg per 5 mL (Teaspoonful)
• Pain Reliever / Fever Reducer (NSAID)

NDC 21130-660-26
Compare to Children's Motrin® Grape Flavor active ingredient**

Children's
For Ages 2 to 11

Ibuprofen
Oral Suspension

100 mg per 5 mL (Teaspoonful)
• Pain Reliever/Fever Reducer (NSAID)
• Alcohol Free
Lasts Up to 8 Hours
Grape Flavored Liquid

4 FL OZ (120mL)

SAFEWAY®

S 1872
3 21130 77649 9
RD 12111

LOT NO.

EXP.

: 66026 15 C8

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

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Drug Facts (continued)

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Drug Facts (continued)

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Questions or comments?
1-888-SAFEWAY

**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin® Grape Flavor.

Child-Resistant Safety Cap
Read Instructions Carefully
Dosage Cup Included

DISTRIBUTED BY
SAFEWAY INC.
P.O. BOX 99
PLEASANTON, CA 94566-0009
QUALITY & SATISFACTION GUARANTEED OR YOUR MONEY BACK
1-888-SAFEWAY / www.safeway.com

CHILDRENS IBUPROFEN
ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:21130-660
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (IBUPROFEN)	IBUPROFEN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID	
D&C RED NO. 33	
FD&C BLUE NO. 1	
FD&C RED NO. 40	
GLYCERIN	
HIGH FRUCTOSE CORN SYRUP	
HYPROMELLOSES	
POLYSORBATE 80	
WATER	
SODIUM BENZOATE	
SORBITOL	
XANTHAN GUM	

Product Characteristics

Color	PURPLE (opaque)	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-660-26	1 in 1 CARTON		
1		120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074937	05/02/2002	

Labeler - Safeway (009137209)

Revised: 10/2012 Safeway