

## **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

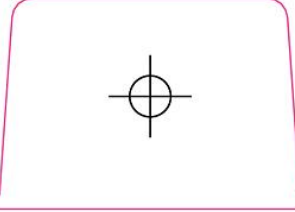
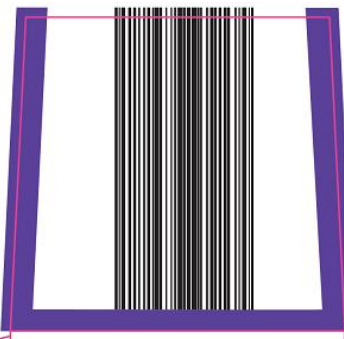
100 mg per 5 mL (Teaspoonful)

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)



**Drug Facts (continued)**

- 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

**Drug Facts (continued)**

**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 1/2 tsp or 7.5 mL
48-59 lbs	6-8 years	2 tsp or 10 mL
60-71 lbs	9-10 years	2 1/2 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

\*\*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

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



**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	Purposes
Ibuprofen 100 mg (NSAID)	Pain reliever/fever reducer

\*nonsteroidal anti-inflammatory drug

**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

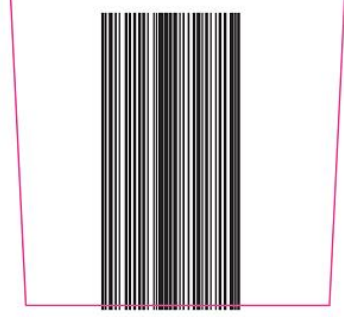
**Sore throat warning:** Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.

**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



4 FL OZ (120mL)

**SAFEWAY**

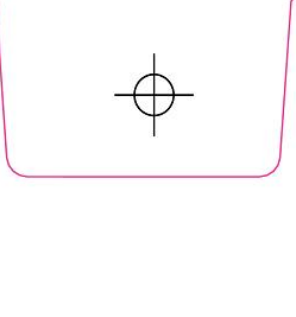


3 21130 77649 9  
RD 12111

LOT NO.

EXP.

: 66026 15 C6



CHILDRENS IBUPROFEN			
ibuprofen suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-660
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	100 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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	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