# SIGNATURE CARE CHILDRENS IBUPROFEN- ibuprofen suspension Safeway

-----

# Better Living Brands LLC 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 ibuprofen or 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

<sup>\*\*</sup>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?

1-888-723-3929

# **Principal Display Panel**

Compare to Children's Motrin® Bubble Gum Flavor active ingredient

Quality Guaranteed

FOR AGES 2 TO 11 YEARS

Children's

Ibuprofen

ORAL SUSPENSION

100 mg PER 5 mL

Pain Reliever/Fever Reducer (NSAID)

BUBBLE GUM FLAVOR

Lasts up to 8 hours

Alcohol free

GLUTEN FREE

4 FL OZ (118 mL)

SEE NEW WARNINGS



Pain Reliever/Fever Reducer (NSAID) 100 mg PER 5 mL **ORAL SUSPENSION** 

# Ibuprofen Children's









Quality Guaranteed

AGES 2 to 11 YEARS

# Children's **Ibuprofen**

**ORAL SUSPENSION** 100 mg PER 5 mL

Pain Reliever/Fever Reducer (NSAID)

# **BUBBLE GUM**

- Lasts up to 8 hours Alcohol free
- GLUTEN FREE

4 FL OZ (118 mL)

**SEE NEW** WARNINGS 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) Ibuprofen 100 mg (NSAID)\*.. .Pain reliever/

fever reducer \*nonsteroidal anti-inflammatory drug

- Uses temporarily:
   relievee 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:

facial swelling

- hives facial swelling asthma (wheezing) shock

Purposes

■ astrnna (wneezing) ■ snock
■ 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 vour child:

- your cniid: has had stomach ulcers or bleeding problems takes a blood thinning (anticoagulant) or
- takes a blood trinning (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 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 wears of any unless directed by doctor. under 3 years of age unless directed by doctor.
- Do not use
- if the child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer

### Drug Facts (continued)

■ 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,

- child has a history of stornach problems, such as hearthurn
   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 chick nas symptoms of neart problems 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 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 direction or complete warnings for adult use do not give more than directed

### Drug Facts (continued)

- shake well before using
- mL = milliliter
- mt. = 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 prose these 4 times expenses.
- do not use more than 4 times a day
   replace original bottle cap to maintain child resistance
   wash dosage cup after each use

### Doeing 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? 1-888-723-3929

<sup>†</sup>This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Children's Motrin® Bubble Gum Flavor.

DISTRIBUTED BY: BETTER LIVING BRANDS LLC P.O. BOX 99, PLEASANTON. CA 94566-0009 1-888-723-3929



www.betterlivingbrandsLLC.com OUR PROMISE QUALITY & SATISFACTION 100% GUARANTEED OR YOUR MONEY BACK.





16626 LJ C3

# SIGNATURE CARE CHILDRENS IBUPROFEN

ibuprofen suspension

## **Product Information** HUMAN OTC DRUG NDC:21130-011 Product Type Item Code (Source) ORAL Route of Administration

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	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)		
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	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:21130-011-26	1 in 1 CARTON	09/01/2015	
1	1	118 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	09/01/2015	

# **Labeler -** Safeway (009137209)

Revised: 11/2017 Safeway