PROFEN IB- ibuprofen suspension Publix Super Markets Inc

Publix Super Markets, Inc. Children's Profen IB 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) under 2 years		Dose (teaspoonful or mL)	
		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, 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

Principal Display Panel

FOR AGES 2 TO 11

CHILDREN'S

profen IB

IBUPROFEN ORAL SUSPENSION

100mg PER 5mL (TEASPOONFUL)

PAIN RELIEVER

FEVER REDUCER (NSAID)

lasts up to 8 hours

alcohol free

BUBBLE GUM FLAVOR

Compare to Active Ingredient in Children's Motrin® Bubble Gum Flavor







IBUPROFEN ORAL SUSPENSION

Drug Facts (continued)

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

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PUBLIX GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK



NDC 56062-166-26

FOR AGES 2 TO 11 CHILDREN'S

IBUPROFEN ORAL SUSPENSION

100mg PER 5mL (TEASPOONFUL)

PAIN RELIEVER FEVER REDUCER (NSAID)

- lasts up to 8 hours
- alcohol free

BUBBLE GUM FLAVOR



**Compare to Active Ingredient in Children's Motrin® Bubble Gum Flavor

4 FL OZ (120 mL)

Drug Facts

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.Pain reliever fever reduce nonsteroidal anti-inflammatory drug

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- and toothache ■ reduces fever

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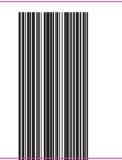
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 child has a history of stomach problems,
- such as heartburn





LOT NO.

EXP.

: JPPSP P3 C9



PROFEN IB

ibuprofen suspension

Product Information

HUMAN OTC DRUG LABEL NDC:56062-166 Product Type Item Code (Source) 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	
ANHYDRO US CITRIC ACID		
FD&C RED NO. 40		
GLYCERIN		
HIGH FRUCTOSE CORN SYRUP		
HYPROMELLOSES		
POLYSORBATE 80		
WATER		
SO DIUM BENZO ATE		
SORBITOL		
XANTHAN GUM		

Product Characteristics			
Color	PINK (light)	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:56062-166-26	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	11/18/2003		

Labeler - Publix Super Markets Inc (006922009)

Revised: 1/2013 Publix Super Markets Inc