

**TOPCARE CHILDRENS IBUPROFEN- ibuprofen suspension**  
**Topco Associates LLC**

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**Topco Associates LLC. 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
- {safety} sealed with printed neckband for your protection. If missing or broken return to store.
- 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?

1-888-423-0139

**Principal Display Panel**

FOR AGES 2 TO 11 YEARS

Children's Ibuprofen Oral Suspension

100 mg per 5 mL

Pain Reliever/Fever Reducer (NSAID)

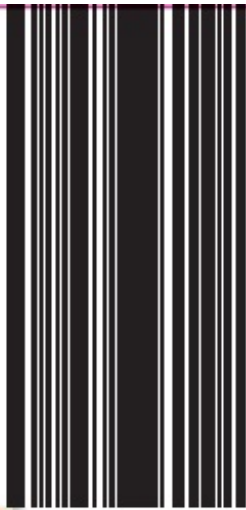
Lasts up to 8 hours

Alcohol free

BUBBLE GUM FLAVOR

COMPARE TO CHILDREN'S MOTRIN® BUBBLE GUM FLAVOR active ingredient

4 FL OZ (120 mL)



NDC 36800-166-26

**TopCare®**

FOR AGES 2 TO 11 YEARS

# Children's Ibuprofen Oral Suspension

100 mg per 5 mL

**Pain Reliever/  
Fever Reducer  
(NSAID)**

- Lasts up to 8 hours
- Alcohol free



**BUBBLE  
GUM  
FLAVOR**



COMPARE TO  
CHILDREN'S MOTRIN®  
BUBBLE GUM FLAVOR  
active ingredient\*

4 FL OZ (120 mL)

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

### Drug Facts

<b>Active ingredient</b> (in each 5 mL = 1 teaspoonful)	<b>Purposes</b>
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          |                   |

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### 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

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 SUSTAINABLE  
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BUBBLE GUM  
FLAVOR

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

Oral Suspension  
**Ibuprofen**  
Children's

FOR AGES 2 TO 11 YEARS

**TopCare**<sup>®</sup>

### 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
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### Drug Facts (continued)

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**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?

1-888-423-0139

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

**GLUTEN FREE**



This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

DISTRIBUTED BY TOPCO ASSOCIATES LLC  
ELK GROVE VILLAGE, IL 60007  
©TOPCO PER1015  
QUESTIONS? 1-888-423-0139  
topcare@topco.com  
www.topcarebrand.com



LOT NO.

EXP.

: 16626 88 C8

## TOPCARE CHILDRENS IBUPROFEN

ibuprofen suspension

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-166
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:36800-166-26	1 in 1 CARTON		
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-166-28	1 in 1 CARTON		
2		150 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	07/30/2002	

**Labeler** - Topco Associates LLC (006935977)

Revised: 2/2016

Topco Associates LLC