# 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

### **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 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

### Questions or comments?

1-888-423-0139

### **Principal Display Panel**

FOR AGES 2 TO 11

Children's Ibuprofen Oral Suspension

100 mg per 5 mL (teaspoonful)

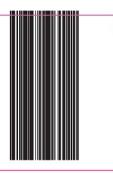
Pain Reliever/Fever Reducer (NSAID)

Lasts up to 8 hours

Alcohol free

**BUBBLE GUM FLAVOR** 

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





# Children's **Ibuprofen**

### **Oral Suspension**

100 mg per 5 mL (teaspoonful)

Pain Reliever/ **Fever Reducer** (NSAID) BUBBLE GUM FLAVOR



#### Drug Facts (continued)

- child has problems or serious side effects
- 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 is tking a diuretic.
- 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

- 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

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- painful area

   any new symptoms appear

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#### **Directions**

- 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
- wash dosage cup after each use

### Drug Facts (continued)

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#### 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,

### ( Questions or comments?

"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 7711 GROSS POINT ROAD SKOKIE, IL 60077 ©TOPCO PER412 topcare@topco.com

## NDC 36800-166-26

# Children's **Ibuprofen Oral** Suspension

100 mg per 5 mL (teaspoonful)

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

- · Lasts up to 8 hours
- Alcohol free



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 (in each 5 mL = 1 teaspoonful)
Ibuprofen 100 mg (NSAID)\*.........Pain reliever

fever reduce \*nonsteroidal anti-inflammatory drug

- Uses temporarily:
   relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache
- reduces fever

Warmings
Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
■ hives
■ asthma (wheezing)
■ skin reddening
■ rash

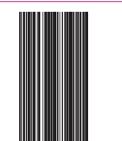
■ skin reddening ■ rash
■ blisters
If an allergic reaction occurs, stop use and
seek medical help right away.
Stomach bleeding warning: This product
contains an NSAID, which may cause severe
stomach bleeding.
The chance is higher if your child:
■ has had stomach ulcers or bleeding problems
■ takes a blood thinning (anticoagulant) or
steroid flura

- 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 vomitting 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

- 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





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LOT NO.

EXP.

: 16626 88 C7



### TOPCARE CHILDRENS IBUPROFEN

ibuprofen suspension

### **Product Information**

HUMAN OTC DRUG LABEL NDC:36800-166 Product Type Item Code (Source) ORAL Route of Administration **DEA Schedule** 

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPRO FEN (IBUPRO FEN)	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:36800-166-26	1 in 1 CARTON		
1		120 mL in 1 BOTTLE		
2	NDC:36800-166-28	1 in 1 CARTON		
2		150 mL in 1 BOTTLE		

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: 4/2013 Topco Associates LLC