# EQUATE IBUPROFEN CHILDRENS- ibuprofen suspension Wal-Mart Stores Inc

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# Wal-Mart 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
- 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?

1-888-287-1915

# **Principal Display Panel**

Compare to Children's Motrin® Active Ingredient

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** 

4 FL OZ (118 mL)



Ages 2 to 11

# Children's

# **Ibuprofen**

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

NDC 49035-166-26



Compare to Children's Motrin®
Active Ingredient\*\*

Ages 2 to 11

# Children's Ibuprofen

Oral Suspension 100 mg per 5 mL (teaspoonful) Pain Reliever/Fever Reducer

(NSAID)



**Bubble Gum** Flavor

4 FL OZ (118 mL)

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

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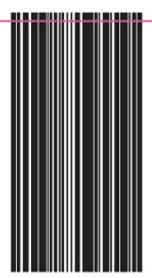
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## Drug Facts (continued)

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#### ( Questions or comments? 1-888-287-1915

Gluten-Free

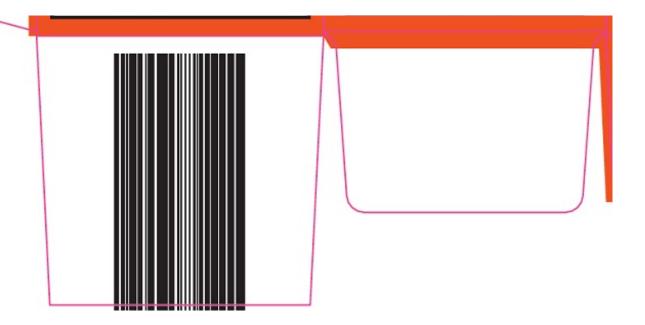


Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call 1-888-287-1915.

Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716.

@ Wal-Mart Stores, Inc.

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



# **EQUATE IBUPROFEN CHILDRENS**

ibuprofen suspension

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:49035-166Route of AdministrationORALDEA Schedule

# **Active Ingredient/Active Moiety**

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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

# Packaging # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:49035-166-26 1 in 1 CARTON

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA074937	04/16/2002		

# Labeler - Wal-Mart Stores Inc (051957769)

118 mL in 1 BOTTLE

**Contains** 

Revised: 6/2014 Wal-Mart Stores Inc