TOPCARE IBUPROFEN- ibuprofen suspension/ drops
Topco Associates LLC

Topco Associates LLC. Ibuprofen Oral Suspension Drug Facts

Active ingredient (in each 1.25 mL)

Ibuprofen 50 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

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
- find right dose on chart below. If possible, use weight to dose; otherwise use age.
- mL = milliliter
- measure with the dosing device provided. Do not use with any other device.
- dispense liquid slowly into the child's mouth, toward the inner cheek
- if needed, repeat dose every **6-8 hours**
- do not use more than **4 times a day**

Dosing Chart

Weight (lbs)	Age (mos)	Dose (mL)
under 6 mos		ask a doctor
12-17 lbs	6-11 mos	1.25 mL
18-23 lbs	12-23 mos	1.875 mL

Other information

- store at 20-25°C (68-77°F)
- do not freeze
- **do not use if printed neckband is broken or missing**

Inactive ingredients

anhydrous citric acid, glycerin, hypromellose, natural and artificial berry flavor, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

Questions or comments?

1-888-423-0139

Principal Display Panel

TopCare_® health

COMPARE TO MOTRIN® INFANTS' DROPS

DYE-FREE ACTIVE INGREDIENT

FOR AGES 6 MOS. TO 23 MOS.

CONCENTRATED DROPS

infants' Ibuprofen

ORAL SUSPENSION

50 mg per 1.25 mL

PAIN RELIEVER

FEVER REDUCER (NSAID)

DYE-FREE

Lasts up to 8 HOURS

• Non-Staining

• No High Fructose Corn Syrup

Use only with enclosed syringe.

Ages 6 mos. to 23 mos.

DYE-FREE BERRY FLAVOR

1 FL OZ (30 mL)

+TopCare®
health

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1 FL OZ (30 mL)

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actual size

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
©TOPCO PERA0521
QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com

Scan here for more information or call 1-888-423-0139

Important: Read all product information before using. Keep this box for important information. This product is intended for use in children ages 6 months to 23 months of age.

Drug Facts

Active ingredient (in each 1.25 mL)	Purposes
Ibuprofen 50 mg (NSAID)*..............Pain reliever/fever reducer	
*nonsteroidal anti-inflammatory drug	

Uses temporarily: ■ reduces fever
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Drug Facts (continued)

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Drug Facts (continued)

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Questions or comments?
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GLUTEN FREE
✓QUALITY GUARANTEED

**This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Motrin® Infants' Drops Dye-Free.

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TOPCARE IBUPROFEN
ibuprofen suspension/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-255
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	50 mg in 1.25 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (Opaque)	Score	
Shape		Size	
Flavor	BERRY (mixed)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-255-10	1 in 1 CARTON	09/10/2004	
1		30 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	ANDA075217	09/10/2004	

Labeler - Topco Associates LLC (006935977)

Revised: 1/2023

Topco Associates LLC