

SHOPRITE INFANTS IBUPROFEN- ibuprofen suspension/ drops
Wakefern Food Corporation

ShopRite Infants Ibuprofen 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

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 below. If possible, use weight to dose; otherwise use age.

- 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
- see bottom of box for lot number and expiration date

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?

1-800-SHOPRITE

Principal Display Panel

Compare to Active Ingredient in Motrin® Infants' Drops
Infants'

FOR AGES 6 TO 23 MOS.

IBUPROFEN

Oral Suspension

50 mg per 1.25 mL

Pain Reliever – Fever Reducer
(NSAID)

LASTS UP TO 8 HOURS

Concentrated Drops

Non-Staining

Dye Free

Gluten Free

No High Fructose Corn Syrup

Berry flavor

Use only with enclosed syringe

1 FL OZ (30 mL)



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ShopRite®

Infants'

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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 **Purposes (in each 1.25 mL)**

Ibuprofen 50 mg Pain reliever/ (NSAID)*...fever reducer
*nonsteroidal anti-inflammatory drug

Uses temporarily:

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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.

Drug Facts (continued)

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Drug Facts (continued)

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Questions or comments?
1-800-SHOPRITE

**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Motrin® Infants' Drops.

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Kearny, NJ 08832 ©2015

QUALITY GUARANTEE

Your complete satisfaction or your money back.
We welcome your questions and comments.
Call: 1-800-ShopRite or contact us:
www.shoprite.com



LOT NO.

EXP.

25510 88 C2



SHOPRITE INFANTS IBUPROFEN

ibuprofen suspension/ drops

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41190-255

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)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
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:41190-255-10	1 in 1 CARTON	06/17/2013	
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	06/17/2013	

Labeler - Wakefern Food Corporation (069722418)

Revised: 12/2019

Wakefern Food Corporation