IBUPROFEN INFANTS- ibuprofen suspension HyVee Inc

Hy-Vee, Inc. Infant's 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 the 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 (lb)	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

- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- do not freeze
- see bottom of box for lot number and expiration date

Inactive ingredients

anhydrous citric acid, artificial flavor, butylparaben, FD&C red #40, glycerin, hypromellose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

Questions or comments?

1-800-719-9260

Principal Display Panel

See New Warnings Information

Compare to Motrin® Infants' Drops Berry Flavor active ingredient

CONCENTRATED DROPS

For Ages 6 Mos. to 23 Mos.

Infants' Ibuprofen

Oral Suspension

50 mg per 1.25 mL

Pain Reliever/Fever Reducer (NSAID)

Alcohol Free

Berry Flavored Drops

Lasts Up To 8 Hours

No High Fructose Corn Syrup

Use Only With Enclosed Syringe

For Ages 6 Mos. to 23 Mos.

Oral Suspension • 50 mg per 1.25 mL Pain Reliever/Fever Reducer (NSAID) Child Resistant Safety Cap . Read Instructions Carefully

See New Warnings Information

NDC 42507-057-05

Compare to Motrin® Infants' Drops Berry Flavor active ingredient

CONCENTRATED DROPS

For Ages 6 Mos. to 23 Mos.

Oral Suspension 50 mg per 1.25 mL

Pain Reliever/Fever Reducer (NSAID)

• Alcohol Free • Berry Flavored Drops

· Lasts Up To 8 Hours





.5 FL OZ (15 mL)

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

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Purposes

Ibuprofen 50 mg

Pain reliever/ (NSAID)*.....fever reducer

'nonsteroidal anti-inflammatory drug

Uses temporarily: ■ reduces fever ■ relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

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Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives ■ facial swelling

■ asthma (wheezing)
■ shock

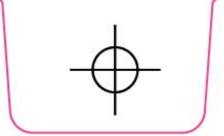
skin reddening rash blisters
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LOT NO.

EXP.

: 05705 2H C7





Drug Facts (continued)

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
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Drug Facts (continued)

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C Questions or comments?

GLUTEN FREE

DISTRIBUTED BY HY-VEE, INC. 5820 WESTOWN PARKWAY WEST DES MOINES, IA 50266 SATISFACTION GUARANTEED OR PURCHASE PRICE REFUNDED FOR INFORMATION CALL 1-800-289-8343 www.hy-vee.com



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IBUPROFEN INFANTS

ibuprofen suspension

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:42507-057	
Route of Administration	ORAL	DEA Schedule		

Active Ingredient/Active Moiety				
Ingredient Name Basis of Strength Strength				
IBUPRO FEN (IBUPRO FEN)	IBUPROFEN	50 mg in 1.25 mL		

Inactive Ingredients				
Ingredient Name	Strength			
ANHYDRO US CITRIC ACID				
BUTYLPARABEN				
FD&C RED NO. 40				
GLYCERIN				
HYPROMELLOSES				
POLYSORBATE 80				
PROPYLENE GLYCOL				
WATER				
SO DIUM BENZO ATE				
SORBITOL				
SUCROSE				
XANTHAN GUM				

Product Characteristics				
Color	PINK (light)	Score		
Shape		Size		
Flavor	FRUIT (mixed)	Imprint Code		
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:42507-057-05	1 in 1 CARTON			

1		15 mL in 1 BOTTLE	
2	NDC:42507-057-10	1 in 1 CARTON	
2		30 mL in 1 BOTTLE	

Marketing Information				
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Da				
ANDA	ANDA075217	09/03/2000		

Labeler - HyVee Inc (006925671)

Revised: 10/2012 HyVee Inc