# HEALTH SENSE INFANTS IBUPROFEN ORAL SUSPENSION- ibuprofen suspension Dolgencorp Inc

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## Dollar General Health Sense Infants' Ibuprofen Oral Suspension, Berry Flavor Drug Facts

## Active ingredient (in each 1.25 mL)

Ibuprofen 50 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

#### **Purpose**

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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause 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 an NSAID [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 the child has

- problems or serious side effects from taking pain relievers or fever reducers
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- ulcers
- bleeding problems
- not been drinking fluids
- lost a lot of fluid due to vomiting or diarrhea
- high blood pressure
- heart or kidney disease
- taken a diuretic

## Ask a doctor or pharmacist before use if the child is

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- 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
- long term continuous use may increase the risk of heart attack or stroke

#### Stop use and ask a doctor if

- the child feels faint, vomits blood, or has bloody or black stools. These are signs of stomach bleeding.
- stomach pain or upset gets worse or lasts
- 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.

#### **Directions**

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- do not give longer than 10 days, unless directed by a doctor (see Warnings)
- shake well before using
- find the right dose on chart below. If possible, use weight to dose; otherwise use age.
- measure with 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)	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

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

# **Inactive ingredients**

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

#### Questions or comments?

1-888-309-9030

# **Principal Display Panel**

Compare to active ingredient of Motrin® Infants' Drops

Concentrated

For Ages 6 mos.-23 mos.

Infants' Ibuprofen Oral Suspension

50 mg per 1.25 mL

Pain Reliever/Fever Reducer (NSAID)

Lasts up to 8 hours

Alcohol Free

Use Only With Enclosed Syringe

Berry Flavor



**Product Carton** 



#### **Product Label**

## HEALTH SENSE INFANTS IBUPROFEN ORAL SUSPENSION

ibuprofen suspension

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55910-057

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

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Ingredient Name	Basis of Strength	Strength
IBUPRO FEN (UNII: WK2XYI10 OM) (IBUPRO FEN - UNII: WK2XYI10 OM)	IBUPROFEN	50 mg in 1.25 mL

#### Product Characteristics

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Color	PINK (light)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

#### **Packaging**

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55910-057-05	1 in 1 CARTON				
1		15 mL in 1 BOTTLE				

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075217	06/08/2009	

# Labeler - Dolgencorp Inc (068331990)

Revised: 5/2009 Dolgencorp Inc