# GOOD SENSE IBUPROFEN- ibuprofen suspension L. Perrigo Company

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#### Perrigo Children's Ibuprofen Oral Suspension Drug Facts

### Active ingredient (in each 5 mL)

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

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
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed dosing cup. Do not use any other dosing device.
- 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

<b>Dosing Chart</b>			
Weight (lb)	Age (yr)	Dose (mL)**	
under 24 lbs	under 2 years	ask a doctor	
24-35 lbs	2-3 years	5 mL	
36-47 lbs	4-5 years	7.5 mL	
48-59 lbs	6-8 years	10 mL	
60-71 lbs	9-10 years	12.5 mL	
72-95 lbs	11 years	15 mL	

<sup>\*\*</sup>or as directed by a doctor

#### Other information

- each 5 mL 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

## **Inactive ingredients**

anhydrous citric acid, artificial mixed berry flavor, glycerin, high fructose corn syrup, hypromellose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

#### Questions or comments?

1-800-719-9260

#### **Principal Display Panel**

For Ages 2 to 11 Years

See New Warnings

Children's Ibuprofen

Oral Suspension 100 mg per 5 mL

Pain Reliever

Fever Reducer (NSAID)

Dye-Free

Non-Staining

Lasts Up To 8 Hours

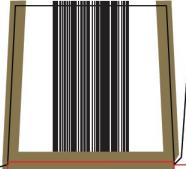
Alcohol Free

Berry Flavor

Compare to active ingredient of Children's Motrin® Dye-Free

100% SATISFACTION GUARANTEED

4 FL OZ (120 mL)



Pain Reliever Fever Reducer (**NSAID**)

Oral Suspension uətoxdna Childrens

#### **COODSEASE®**

## GOODSENSE.

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Children's Motrin® Dye-Free

4 FL 0Z (120 mL)

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

#### Drug Facts

Active ingredient (in each 5 mL) Ibuprofen 100 mg (NSAID)\*... .Pain reliever

fever reducer nonsteroidal anti-inflammatory drug

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   relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache ■ reduces fever

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#### Drug Facts (continued)

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Ask a doctor or pharmacist before use if

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- When using this product give with food or milk if stomach upset occurs

Stop use and ask a doctor if

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   replace against bottle age to maintain.
- replace original bottle cap to maintain child resistance
   wash dosage cup after each use

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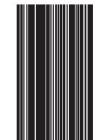
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# Inactive ingredients anhydrous citric acid, artificial mixed berry flavor, glycerin, high fructose corn syrup, hypromellose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments? 1-800-719-9260

Gluten Free

Distributed By Perrigo<sup>®</sup> Allegan, MI 49010





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#### GOOD SENSE IBUPROFEN

ibuprofen suspension

#### **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0113-0685

Route of Administration

ORAL

**Active Ingredient/Active Moiety** 

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0113-0685-26	1 in 1 CARTON	04/28/2011	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0113-0685-34	1 in 1 CARTON	03/16/2015	
2		240 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	ANDA074937	04/28/2011	

# Labeler - L. Perrigo Company (006013346)

Revised: 12/2017 L. Perrigo Company