# GOOD SENSE IBUPROFEN CHILDRENS- 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

## **Dosing Chart**

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, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, natural and artificial bubblegum flavors, 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)

Lasts Up To 8 Hours

Alcohol Free

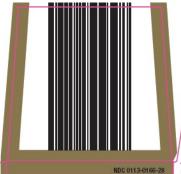
Bubble Gum Flavor

Compare to active ingredient of Children's Motrin®

100% SATISFACTION GUARANTEED

BONUS SIZE 4 + 1 OZ FREE

5 FL OZ (150 mL)



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Oral Suspension 100 mg per 5 mL <u>uətoxana</u> s,uaiplin)

### **COODSEASE®**

# GOODSENSE.

For Ages 2 to 11 Years

See New Warnings

# Children's lbuprofen

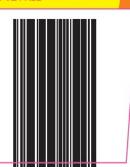
**Oral Suspension** 100 mg per 5 mL

Pain Reliever Fever Reducer (NSAID)



Compare to active in Children's Motrin®





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

Purposes

nonsteroidal anti-inflammatory drug\*

Uses temporarily:
■ relieves minor aches and pains due to the common cold, flu, sore throat, headache

Warnings
Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
■ hives ■ facial swelling
■ sthma (wheezing) ■ shock
■ skin reddening ■ rash

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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:

- your child: has had stomach ulcers or bleeding problems takes a blood thinning (anticoagulant) or

■ 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 he fatel The risk is bidger if you use more. 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 scre 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

#### Drug Facts (continued)

- child has a history of stomach problems,
- child has a history of stomach problems, such as hearburn
   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
- a 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

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   do not give more than directed
- shake well before using mL = milliliter

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   use only enclosed dosing cup. Do not use any other dosing device.
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#### Drug Facts (continued)

■ wash dosage cup after each use Dosing Chart

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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, FD&C ned #40, glycerin, high fructose corn syrup, hypromeliose, natural and artificial bubblegum flavors, polysorbate 80, purified water, sodium berzoate, sorbitol solution, xarithan gum

Questions or comments?

Gluten Free

Distributed By

Perrigo® Allegan, MI 49010

A6830 C2 C3

### GOOD SENSE IBUPROFEN CHILDRENS

ibuprofen suspension

#### **Product Information**

HUMAN OTC DRUG Product Type Item Code (Source) NDC:0113-0166 ORAL Route of Administration

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII:WK2XYI10 QM)	IBUPROFEN	100 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	PINK (light)	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:0113-0166-26	1 in 1 CARTON	05/04/2002	
1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2 NDC:0113-0166-28	1 in 1 CARTON	05/28/2013	
2	150 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3 NDC:0113-0166-34	1 in 1 CARTON	02/11/2020	
3	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	05/04/2002	

# Labeler - L. Perrigo Company (006013346)

Revised: 2/2020 L. Perrigo Company