

GOOD SENSE IBUPROFEN CHILDRENS- ibuprofen suspension
Rebel Distributors Corp

Perrigo Children's Ibuprofen Oral Suspension Drug Facts

Active ingredient (in each 5 mL = 1 teaspoonful)

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

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

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 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. If possible, use weight to dose; otherwise use age.
- use only enclosed measuring cup
- 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 (lbs)	Age(yrs)	Dose (teaspoonful or mL)
under 2 years		ask a doctor
24-35 lbs	2-3 years	1 tsp or 5 mL
36-47 lbs	4-5 years	1 ½ tsp or 7.5 mL
48-59 lbs	6-8 years	2 tsp or 10 mL
60-71 lbs	9-10 years	2 ½ tsp or 12.5 mL

72-95 lbs

11 years

3 tsp or 15 mL

Other information

- each teaspoon contains: **sodium 2 mg**
- **do not use if printed neckband is broken or missing**
- store at 20-25°C (68-77°F)
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, artificial mixed berry flavor, D&C yellow #10, FD&C red #40, 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 2-11

See New Warnings Information

Children's Ibuprofen Oral Suspension

100 mg per 5 mL (Teaspoonful)

Pain Reliever

Fever Reducer (NSAID)

Lasts Up To 8 Hours

Alcohol Free

Berry Flavor

Compare to active ingredient of Children's Motrin®

PHYSICIAN PARTNER
A DIVISION OF REBEL DISTRIBUTORS CORP.

NDC 42254-117-12

Ibuprofen (Children's) 100mg / 5ml

4oz (120ml) Oral Suspension

Each 5ml (1tsp) contains: Ibuprofen 100mg (NSAID) Pain Reliever / Fever Reducer Nonsteroidal Anti-Inflammatory Drug.

For Ages 2-11 / Alcohol free / Berry flavor
(Lasts up to 8 hours)

Product ID: SI011712

Dist. By: Perrigo Allegan, MI 49010

Peel

Ibuprofen (Children's) 100mg / 5ml
4oz (120ml) Oral Suspension Rx# Master
Lot #: 000000 Exp. Date: 00/00/00
NDC 42254-117-12 AWP: \$24.44

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Ibuprofen (Children's) 100mg / 5ml
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RX#Master

Distributed by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com
Store at controlled room temperature 15°-30° C (59°-86° F) Keep medication out of the reach of children.

GOOD SENSE IBUPROFEN CHILDRENS			
ibuprofen suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42254-117(NDC:0 113-0897)
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	
	ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
	GLYCERIN (UNII: PDC6A3C0OX)		
	HYPROMELLOSES (UNII: 3NXW29V3WO)		
	POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
	WATER (UNII: 059QF0K00R)		

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-117-12	1 in 1 CARTON		
1		120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074937	01/07/1999	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2012

Rebel Distributors Corp