IBUPROFEN- ibuprofen suspension Padagis Israel Pharmaceuticals Ltd

Perrigo 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 | under 2 | ask a doctor | |
| lbs | years | | |
| 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 | |

^{**}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, 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

Compare to Children's Motrin® active ingredient

Children's Ibuprofen

Oral Suspension

100 mg per 5 mL

Pain Reliever/Fever Reducer

(NSAID)

For Ages 2 to 11 Years

Lasts up to 8 Hours

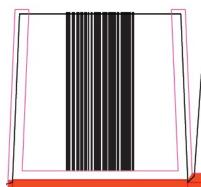
Alcohol Free

Gluten Free

Berry Flavor

See New Warnings

8 FL OZ (237 mL)



(GIASN) Pain Reliever/Fever Reducer

100mg per 5mL

noisnaqsu2 lsi0 **Ibuprofen Children's**

NDC 45802-897-34

Compare to Children's Motrin

Perrigo®

NDC 45802-897-34

Children's **Ibuprofen Oral Suspension**

100 mg per 5 mL

Pain Reliever/Fever Reducer (NSAID)

- ✓ For Ages 2 to 11 Years
- ✓ Lasts up to 8 Hours
- ✓ Alcohol Free
- ✓ Gluten Free

Berry Flavor



See New Warnings

8 FL 0Z (237 mL)

Compare to Children's Motrin®

Perrigo®

NDC 45802-897-34

Children's **Ibuprofen** Oral Suspension

100 mg per 5 mL

Pain Reliever/Fever Reducer (NSAID)

⊘FSA

If your doctor writes a prescription for this product, it may be covered by

FSA or HSA Accounts

Private Health Plans ✓ Medicaid/Medicare

When public and private health plans provide coverage for OTC pharmaceuticals, consumers get relief and drug formularies can reduce costs.

At Perrigo, we call it ORx

Perrigo® Allegan, MI 49010 . www.perrigo.com 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)*...

Purposes

*nonsteroidal anti-inflammatory drug

Uses temporarily:

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

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- 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

Drug Facts (continued)

When using this product
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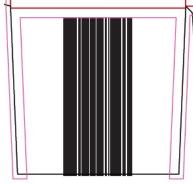
- Other information

 each 5 mL contains: sodium 2 mg

 do not use if printed neckband is broken or missing missing store at 20-25°C (68-77°F)

Inactive ingredients anhydrous citric acid, artificial mixed berry flavor, D&C yellow #10, FD&C red #40, glycerin, high fructose corn syrup, hypromelices, polysorbate 80, purified water, sodiur benzoate, sorbitol solution, xanthan gum

Questions or comments? 1-800-719-9260





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IBUPROFEN

ibuprofen suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:45802-897

| 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) | | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | |
| POLYSORBATE 80 (UNII: 60ZP39ZG8H) | | |
| WATER (UNII: 059QF0KO0R) | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | |

| Product Characteristics | | | |
|-------------------------|--------|--------------|--|
| Color | ORANGE | Score | |
| Shape | | Size | |
| Flavor | BERRY | Imprint Code | |
| Contains | | | |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:45802-897- 26 | 1 in 1 CARTON | 11/17/2011 | |
| 1 | | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:45802-897- 34 | 1 in 1 CARTON | 04/09/2014 | |
| 2 | | 237 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 | 11/17/2011 | |
| | | | |

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 11/2021

Padagis Israel Pharmaceuticals Ltd