

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 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

**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)



Compare to Children's Motrin® active ingredient

Compare to Children's Motrin® active ingredient

Perrigo®

NDC 45802-897-34

Children's Ibuprofen Oral Suspension

100mg 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)

Perrigo®

NDC 45802-897-34

Children's Ibuprofen Oral Suspension

100mg per 5 mL

Pain Reliever/Fever Reducer (NSAID)



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.

Distributed By

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)*.....Pain reliever/fever reducer

Purposes
*nonsteroidal anti-inflammatory drug

Uses temporarily:
relieve minor aches and pains due to the common cold, flu, sore throat, headache and toothache
reduce fever

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

Pain Reliever/Fever Reducer (NSAID)
100mg per 5 mL
Ibuprofen Oral Suspension
Children's
NDC 45802-897-34

Drug Facts (continued)

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 dosing 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

**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, polyorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments? 1-800-719-9260

89734 RT C3

IBUPROFEN

ibuprofen suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:45802-897

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)	
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: 6OZP39ZG8H)	
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			

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	

Revised: 11/2021

Padagis Israel Pharmaceuticals Ltd