

CHILDRENS IBUPROFEN ORAL SUSPENSION ORIGINAL BERRY FLAVOR-
ibuprofen suspension
Puro Pharma Inc.

Children's Ibuprofen Oral Suspension Original Berry Flavor

Drug Facts

Active ingredient
(in each 5 mL)

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

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

- take 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

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	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
- store between 20-25° C (68-77° F)
- **do not use if carton is opened or printed bottle neckband is broken or missing**
- see bottom panel for lot number and expiration date

Inactive ingredients

Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

Questions or comments?

Call weekdays from 9:30 AM to 4:30 PM EST at
1-732-314-4550

**Package Labeling PURO PHARMA Children's Ibuprofen Oral Suspension
Original Berry Flavor**

PURO

NDC 83474-002-04

PHARMA

COMPARE TO THE

ACTIVE INGREDIENT

IN CHILDREN'S

MOTRIN®**

Children's

Ibuprofen

Oral Suspension (NSAID)

100 mg per 5 ml

FOR AGES 2 TO 11 YEARS

Pain Reliever

Fever Reducer

LASTS UP TO 8 HOURS

Original

Berry Flavor

4 FL OZ (118 mL)

Important Read all product information before using.

Keep this box for important information.

This product is intended for use in children.

****This product is not manufactured or distributed by McNeil**

Consumer Healthcare, distributor of Children's Motrin[®]

Distributed by:

Puro Pharma Inc.

42 Catharine St. Poughkeepsie, NY 12601

Info@puro-pharma.com

BX-174

NO VARNISH

Drug Facts (continued)

- 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

- Take 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
- Read 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

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	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
72-85 lbs	11 years	15 mL

*or as directed by a doctor

Drug Facts (continued)

- Other information**
- each 5 mL contains: sodium 2 mg
 - store between 20-25 °C (68-77 °F)
 - do not use if carton is opened or printed bottle neckband is broken or missing
 - see bottom panel for lot number and expiration date

Inactive ingredients

Acosulfate potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, Flavors, glycerin, microcrystalline cellulose, polyvinylpyrrolidone 80, propylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

Questions or comments?

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BX-174

PURO PHARMA

NDC 83474-002-04

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

NDC 83474-002-04

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S MOTIN®**

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

FOR AGES 2 TO 11 YEARS

Pain Reliever
Fever Reducer

LASTS UP TO 8 HOURS



ORIGINAL
Berry Flavor

4 FL OZ (118 mL)



NO VARNISH

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 Purpose
(in each 5 mL)
Ibuprofen 100 mg NSAID Pain reliever
nonsteroidal anti-inflammatory drug 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
- swelling (behind) eye
- stomach
- skin redness
- rash
- itching

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 7 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

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NDC 83474-002-04

Drug Facts

Active ingredient Purpose (in each 5 mL)

Ibuprofen 100 mg (NSAID)*..... Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

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** ■ take 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



NO VARNISH



Drug Facts (continued)

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 below. 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

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Other information ■ each 5 mL contains: sodium 2 mg ■ store between 20-25 °C (68-77 °F) ■ do not use if printed neckband is broken or missing

Inactive ingredients Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose and xanthan gum

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CHILDRENS IBUPROFEN ORAL SUSPENSION ORIGINAL BERRY FLAVOR

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83474-002
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor	BERRY (Original Berry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83474-002-04	1 in 1 CARTON	03/28/2024	
1		118 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	ANDA210602	03/28/2024	

Labeler - Puro Pharma Inc. (128518845)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(83474-002)