

CHILDRENS IBUPROFEN ORAL SUSPENSION DYE FREE- ibuprofen suspension
AptaPharma Inc.

Children's Ibuprofen Oral Suspension, Dye-Free

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 printed neckband is broken or missing**

Inactive ingredients

Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, 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
1-877-798-5944

Package Labeling: Children's Ibuprofen Oral Suspension Original Berry Flavor

See New Warnings

NDC 76281-128-24

AP Safe

**Compare To The
Active Ingredient In
Children's Motrin®****

For Ages 2 to 11 Years

Children's Ibuprofen

Oral Suspension (NSAID)

100 mg per 5 mL

Pain Reliever/Fever Reducer

Dye-Free

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®.**

Manufactured by:

APTAPHARMA Inc.

1533 Union Avenue

Pennsauken, NJ 08110, USA

Carton Label

For Ages 2 to 11 Years

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

Drug Facts (continued)

Read the entire label.

- 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:
 - red stool
 - black, bloody or black stools
 - vomits blood
- child has symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part of 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 AP Poison Control Center right away. (1-800-232-1222)

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 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
saccharin potassium, anhydrous citric acid, carbocymethylcellulose sodium, flavors, glycerin, microcrystalline cellulose, polyethylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

Questions or comments?
Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-798-8944

* This product is not manufactured or distributed by MHMI Consumer Healthcare, distributor of Children's Motrin®.

Manufactured by:
P. P. H. PHARM, Inc.
1533 Wilson's Lane
Westborough, MA 01581, USA © 2008

See New Warnings

NDC 76281-128-24



Compare To The Active Ingredient In Children's Motrin®**

For Ages 2 to 11 Years

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer

Dye-Free

LASTS UP TO 8 HOURS

Original
Berry Flavor

4 FL OZ (118 mL)



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Important: Read all product information before using. Keep this label for important information. This product is intended for use in children.

Drug Facts

Active ingredient (in each 5 mL)	Purpose
Ibuprofen 100 mg (NSAID)	Pain reliever
Nonsteroidal anti-inflammatory drug	Fever reducer

Use temporarily:

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

Warnings
Allergic alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin redness
- rash
- Nitros:
 - nitros

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 you child:

- has had stomach ulcers or bleeding problems
- takes 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. Contact 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 or pharmacist 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 site of fluid due to vomiting or diarrhea
- child has high blood pressure, heart disease, liver disease, kidney disease, or had a stroke

Bottle Label

Important: Read all product information before using. Keep the box for important information. This product is intended for use in children.



NDC 76281-128-24

**Children's
Ibuprofen**

Oral Suspension (NSAID)
100 mg per 5 mL 4 fl.oz
Pain Reliever/Fever Reducer (1.18 mL)

Dye-Free

Original Berry Flavor

Drug Facts

Active ingredient
(in each 5 mL)

Purpose

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

*Nonsteroidal anti-inflammatory drug
Use 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 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



LR-127

Lot/Exp Date

PEEL HERE

Hinge

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

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
printed neckband is broken or missing

Inactive ingredients Acesulfame potassium,
anhydrous citric acid, carboxymethylcellulose sodium,
flavors, glycerin, microcrystalline cellulose, polyacrylate
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 1-877-796-6944

†† This product is not manufactured or distributed by
McNeil Consumer Healthcare, distributor of Children's
Motrin®

Manufactured by:
SPT PHARMS Inc. 1538 Union Avenue
Rensselaer, NJ 08110 USA

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CHILDRENS IBUPROFEN ORAL SUSPENSION DYE FREE

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-128
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: 230V73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
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		Score	
Shape		Size	
Flavor	BERRY (Original Berry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-128-24	1 in 1 CARTON	11/01/2023	
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	09/30/2020	

Labeler - Aptapharma Inc. (790523323)

Registrant - Aptapharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
Aptapharma Inc.		790523323	manufacture(76281-128)

Revised: 12/2025

Aptapharma Inc.