

**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***

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
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 contents of this label carefully.
- Keep this and all other medicines out of the reach of children.
- Do not use if the seal is broken or missing.
- Do not use if the carton is opened or printed bottle neckband is broken or missing.
- See bottom panel for lot number and expiration date.

### 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 stomach pain that does not get better
- 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. (1-800-222-1222)

### 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 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

Acetaminophen, potassium anhydrous citric acid, carbocymethyl cellulose 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 1-877-798-6944

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

Manufactured by:  
P. P. H. 3888, Inc.  
1533 Wilson's Lane  
Westborough, NJ 08110, USA 82-088

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)



3 76281 12824 6

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

Use temporarily:  
Relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache  
Reduces fever

#### Warnings

Ask a doctor if:  
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, 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 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 before or 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

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 or right before or after heart surgery.

**Drug Facts**

**Active ingredient**  
(in each 5 mL)  
Ibuprofen 100 mg (NSAID)

**Purpose**

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

**Children's  
Ibuprofen**

Oral Suspension (NSAID)

100 mg per 5 mL

Pain Reliever/Fever Reducer (1.18 mL)

4 fl.oz

**Dye-Free**

**Original Berry Flavor**

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

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

res

**CHILDRENS IBUPROFEN ORAL SUSPENSION DYE FREE**

ibuprofen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76281-128
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg in 5 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ACESULFAME POTASSIUM</b> (UNII: 230V73Q5G9)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY (Original Berry)	<b>Imprint Code</b>	
<b>Contains</b>			

### 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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA210602	09/30/2020	

**Labeler** - Aptapharma Inc. (790523323)

**Registrant** - Aptapharma Inc. (790523323)

**Establishment**

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

Revised: 11/2023

Aptapharma Inc.