

## **CHILDRENS IBUPROFEN ORAL SUSPENSION, DYE FREE- ibuprofen suspension Best Choice**

### **Children's Ibuprofen Oral Suspension, Dye Free 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***

<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  
**1-732-314-4550**

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**Package Labeling: Best Choice® Children's Ibuprofen Oral Suspension, Dye Free**

**Best Choice®**

**Children's**

**Ibuprofen**

**Oral Suspension (NSAID)**

**100 mg/5 ml**

**Pain Reliever/Fever Reducer**

**LASTS UP TO**

**8 HOURS**

COMPARE TO THE

ACTIVE INGREDIENT  
IN CHILDREN'S  
MOTRIN®\*\*

**For ages**

**2 to 11 years**

**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®**

**PROUDLY DISTRIBUTED BY:**

**VALUE MERCHANDISERS, CO.**

**5000 KANSAS AVE**

**KANSAS CITY, KS 66106**

**Carton**



**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:
  - black stool
  - vomits blood
- 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 cap. 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 resealed to broken or missing
- see bottom panel for lot number and expiration date

**Inactive ingredients**

Acetylsalicylic acid, benzydrous citric acid, carbosymethylcellulose sodium, flavors, glycerin, microcrystalline cellulose, polyvinylpyrrolidone, purified water, sodium benzoate, sucrose, and xanthan gum

**Questions or comments?**  
Call weekdays from 9:30 AM to 4:30 PM EST at 1-732-314-4656

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

PROUDLY DISTRIBUTED BY:  
VALU MERCHANTSERS, CO.  
5000 KANSAS AVE.  
KANSAS CITY, KS 66106

Scan here for more product information.  
Call 1-844-292-1112 for more product information.

**Best Choice.**  
100% Guaranteed

www.bestchoicebrand.com

**PARENTS:**  
Learn about how to use this device.

www.StopMedicineAbuse.org

**Best Choice**  
Dye-Free Children's Ibuprofen

Oral Suspension (NSAID)  
100 mg/5 mL

For ages 2 to 11 years

**Dye Free Original Berry Flavor**

**Best Choice**  
Dye-free Children's Ibuprofen

Oral Suspension (NSAID)  
100 mg/5 mL

**Pain Reliever/Fever Reducer**

**LASTS UP TO 8 HOURS**

See Warnings

For ages 2 to 11 years

**Dye Free Original Berry Flavor**

Use only with enclosed dosing cup. Wash and let air dry after each use.

**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.**

**Drug Facts**

Active ingredient (in each 5 mL)	Purpose
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**

**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 redness
- rash
- stomach pain

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 had 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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735

201611

BX-146

**Bottle**

**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

**Purpose**

\*nonsteroidal anti-inflammatory drug  
**Use when you need it:**  
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, difficulty breathing, dizziness, skin redness, rash, or 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



**Do not use if:** child has had a stomach ulcer or bleeding  
child has had a heart attack or stroke  
child has had a heart problem or heart failure  
child has had a kidney problem or kidney failure  
child has had a liver problem or liver failure  
child has had a blood thinning (anticoagulant) or steroid drug  
child takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)  
child takes more or for a longer time than directed  
child has symptoms of heart problems (swelling, 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 or 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 asthma; 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; skip 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



**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 as 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.

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, carbonylmethylcellulose croscarmellose, fava, glycerin, microcrystalline cellulose, polyorbital 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. This product is not manufactured or distributed by McKelvey Consumer Healthcare, distributor of Children's Motril®. PROUDLY DISTRIBUTED BY: KML MERCHANDISERS, CO. 5000 KANSAS AVE. KANSAS CITY, KS 66116 www.bestchoicebrand.com

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CHILDRENS IBUPROFEN ORAL SUSPENSION, DYE FREE			
ibuprofen suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-128
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	IBUPROFEN (UNII: WK2XY10QM) (IBUPROFEN - UNII:WK2XY10QM)	IBUPROFEN	100 mg in 5 mL
Inactive Ingredients			
	Ingredient Name	Strength	
	ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)		
	ANHYDROUS CITRIC ACID (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:63941-128-24	1 in 1 CARTON	01/01/2025	
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	01/01/2025	

**Labeler** - Best Choice (868703513)

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

### Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(63941-128)

Revised: 1/2025

Best Choice