

**CHILDRENS IBUPROFEN ORAL SUSPENSION- ibuprofen suspension**  
**PAI Holdings, LLC dba PAI Pharma**

-----  
**Children's Ibuprofen Oral Suspension, USP**

***Drug Facts***

***Active ingredient (in each 5 mL)***

Ibuprofen 100 mg (NSAID)<sup>1</sup>

<sup>1</sup>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 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**

<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° to 25°C (68° to 77°F)
- **do not use if carton is opened or if safety seal under cap printed with “SEALED FOR YOUR PROTECTION” is torn or missing**

Children’s Ibuprofen Oral Suspension is a white to off-white suspension supplied in the following:

NDC 0121-0833-04: 4 fl oz (120 mL) bottle

NDC 0121-0833-81: Case contains 12 cartons of NDC 0121-0833-04.

NDC 0121-0833-05: 5 mL unit dose cup.

NDC 0121-0833-00: Case contains 100 unit dose cups of 5 mL packaged in 10 trays of

10 unit dose cups each.

NDC 0121-0833-40: Case contains 40 unit dose cups of 5 mL packaged in 4 trays of 10 unit dose cups each.

NDC 0121-1666-10: 10 mL unit dose cup.

NDC 0121-1666-00: Case contains 100 unit dose cups of 10 mL packaged in 10 trays of 10 unit dose cups each.

NDC 0121-1666-40: Case contains 40 unit dose cups of 10 mL packaged in 4 trays of 10 unit dose cups each.

### ***Inactive ingredients***

avicel, citric acid, glycerin, polysorbate 80, purified water, sodium benzoate, sodium carboxymethylcellulose, sorbitol solution, sucrose, xanthan gum. May contain citric acid and sodium citrate dihydrate for pH adjustment.

### ***Questions or comments?***

Call 1-800-845-8210.

### **MANUFACTURED BY**

PAI Pharma

Greenville, SC 29605

R04/24

### **PRINCIPAL DISPLAY PANEL**

Delivers **5 mL**

NDC 0121-**0833**-05

**CHILDREN'S IBUPROFEN  
ORAL SUSPENSION, USP**

**(NSAID)**

**100 mg per 5 mL**

**SHAKE WELL**

**Alcohol Free/Dye Free**

**For Institutional Use Only**

**Dist. by:** PAI Pharma

Greenville, SC 29605

**SEE DRUG FACTS**



**PRINCIPAL DISPLAY PANEL**

Delivers **10 mL**

NDC 0121-**1666**-10

**CHILDREN'S IBUPROFEN**  
**ORAL SUSPENSION, USP**  
(NSAID)

**200 mg per 10 mL**

**SHAKE WELL**  
**Alcohol Free/Dye Free**

**For Institutional Use Only**

**Dist. by:** PAI Pharma  
Greenville, SC 29605

**SEE DRUG FACTS**



## CHILDRENS IBUPROFEN ORAL SUSPENSION

ibuprofen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0121-0833
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>cellulose, microcrystalline</b> (UNII: OP1R32D61U)	
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>carboxymethylcellulose sodium, unspecified form</b> (UNII: K679OBS311)	
<b>sorbitol solution</b> (UNII: 8KW3E207O2)	

<b>sucrose</b> (UNII: C151H8M554)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>trisodium citrate dihydrate</b> (UNII: B22547B95K)	

### Product Characteristics

<b>Color</b>	white (to off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0833-40	4 in 1 CASE	08/01/2025	
1		10 in 1 TRAY		
1	NDC:0121-0833-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-0833-00	10 in 1 CASE	08/01/2025	
2		10 in 1 TRAY		
2	NDC:0121-0833-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214789	08/01/2025	

## CHILDRENS IBUPROFEN ORAL SUSPENSION

ibuprofen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0121-1666
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Ibuprofen</b> (UNII: WK2XYI10QM) (Ibuprofen - UNII:WK2XYI10QM)	Ibuprofen	200 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

<b>cellulose, microcrystalline</b> (UNII: OP1R32D61U)	
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>glycerin</b> (UNII: PDC6A3C00X)	
<b>polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>carboxymethylcellulose sodium, unspecified form</b> (UNII: K679OBS311)	
<b>sorbitol solution</b> (UNII: 8KW3E207O2)	
<b>sucrose</b> (UNII: C151H8M554)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>trisodium citrate dihydrate</b> (UNII: B22547B95K)	

### Product Characteristics

<b>Color</b>	white (to off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-1666-40	4 in 1 CASE	08/01/2025	
1		10 in 1 TRAY		
1	NDC:0121-1666-10	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-1666-00	10 in 1 CASE	08/01/2025	
2		10 in 1 TRAY		
2	NDC:0121-1666-10	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214789	08/01/2025	

**Labeler** - PAI Holdings, LLC dba PAI Pharma (044940096)