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)[1]

[1]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

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° 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

NDC 0121-**0833**-04

Compare to Children's Motrin® active ingredient**

For Ages 2 to 11 Years

Children's Ibuprofen

Oral Suspension, USP

(NSAID)

100 mg per 5 mL

Pain Reliever/Fever Reducer

Lasts up to
8 hours

Alcohol Free/Dye Free

4 fl oz (120 mL)

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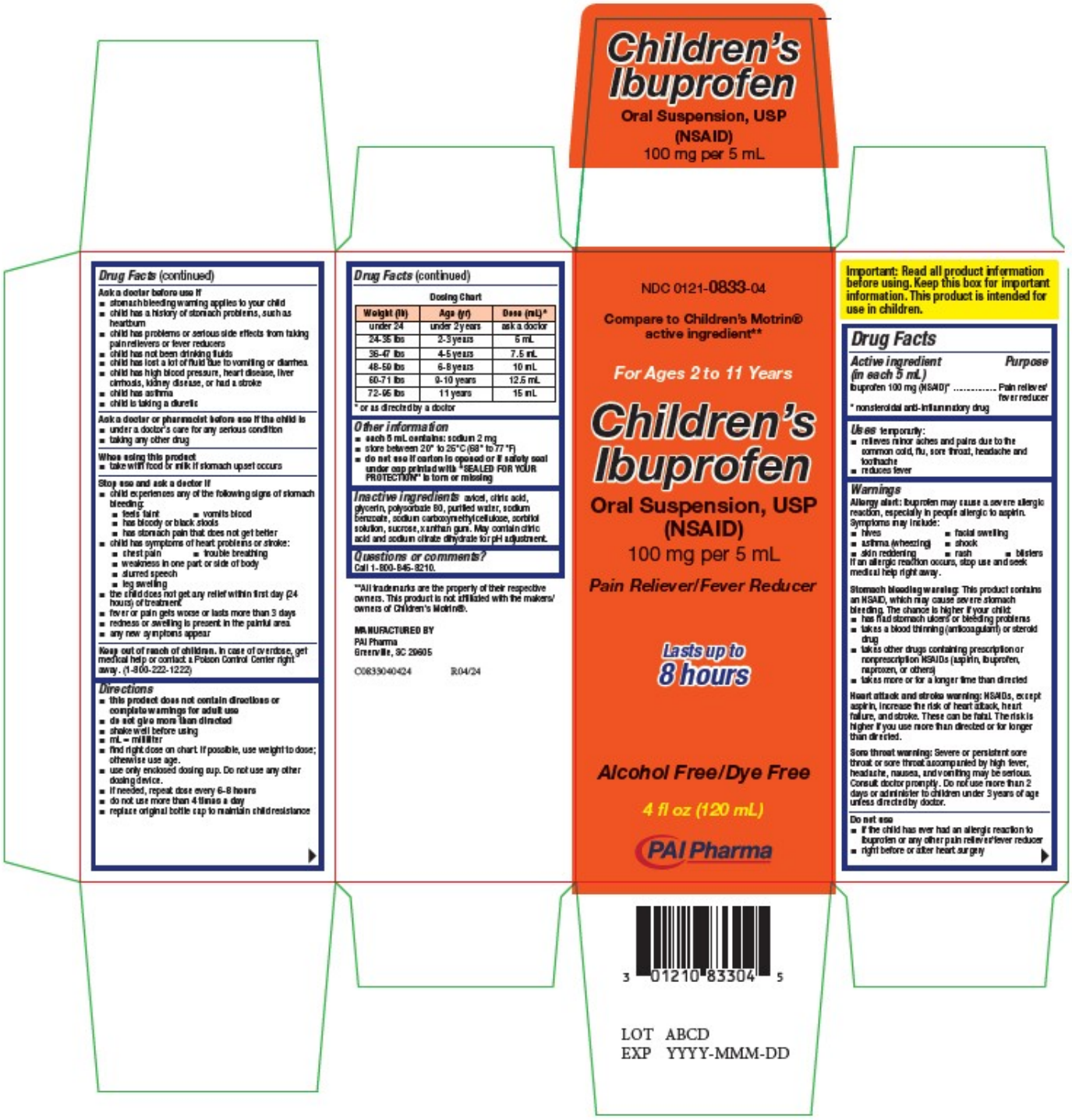


PRINCIPAL DISPLAY PANEL

Delivers **5 mL**

NDC 0121-**0833**-05

CHILDREN'S IBUPROFEN

ORAL SUSPENSION, USP

(NSAID)

100 mg per 5 mL

SHAKE WELL

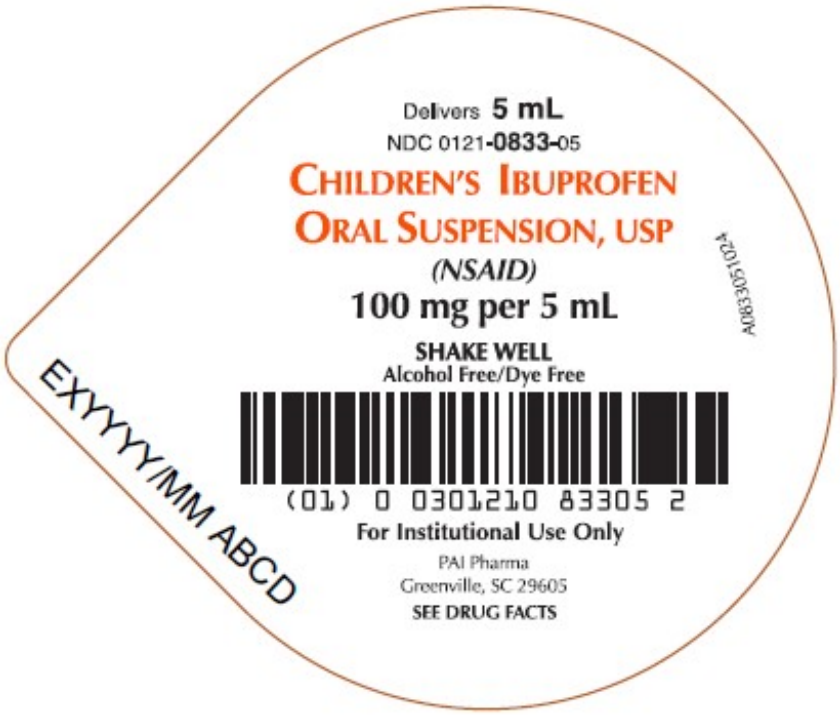
Alcohol Free/Dye Free

For Institutional Use Only

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

PAI Pharma
Greenville, SC 29605

SEE DRUG FACTS

CHILDRENS IBUPROFEN ORAL SUSPENSION

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-0833
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**
cellulose, microcrystalline (UNII: OP1R32D61U)	
anhydrous citric acid (UNII: XF417D3PSL)	
glycerin (UNII: PDC6A3C0OX)	

polysorbate 80 (UNII: 6OZP39ZG8H)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
carboxymethylcellulose sodium, unspecified form (UNII: K679OBS311)	
sorbitol solution (UNII: 8KW3E207O2)	
sucrose (UNII: C151H8M554)	
xanthan gum (UNII: TTV12P4NEE)	
trisodium citrate dihydrate (UNII: B22547B95K)	

Product Characteristics

Color	white (to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0833-81	12 in 1 CASE	05/07/2025	
1		1 in 1 CARTON		
1	NDC:0121-0833-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0121-0833-40	4 in 1 CASE	05/07/2025	
2		10 in 1 TRAY		
2	NDC:0121-0833-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:0121-0833-00	10 in 1 CASE	05/07/2025	
3		10 in 1 TRAY		
3	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	05/07/2025	

CHILDRENS IBUPROFEN ORAL SUSPENSION

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-1666
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
cellulose, microcrystalline (UNII: OP1R32D61U)	
anhydrous citric acid (UNII: XF417D3PSL)	
glycerin (UNII: PDC6A3C0OX)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
carboxymethylcellulose sodium, unspecified form (UNII: K679OBS311)	
sorbitol solution (UNII: 8KW3E207O2)	
sucrose (UNII: C151H8M554)	
xanthan gum (UNII: TTV12P4NEE)	
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Color	white (to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-1666-40	4 in 1 CASE	05/07/2025	
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	05/07/2025	
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	05/07/2025	

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

Revised: 11/2024 PAI Holdings, LLC dba PAI Pharma