

**CHILDRENS IBUPROFEN- ibuprofen suspension**  
**NuCare Pharmaceuticals, Inc.**

-----  
**Ibuprofen Oral Suspension, USP**

***Drug Facts***

***Active ingredient***

**(in each 5 mL)**

Ibuprofen, USP 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° to 25°C (68° to 77°F)
- **do not use if printed neckband is broken or missing**
- see bottom panel for lot number and expiration date

***Inactive ingredients***

Original Berry: citric acid, D&C yellow #10, FD&C red #40, flavors, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

Dye-Free Berry: citric acid, flavors, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

Grape: citric acid, D&C red #33, FD&C blue #1, FD&C red #40, flavors, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

Bubble Gum: artificial bubble gum flavor, citric acid, FD&C red #40, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

**Questions? 1-800-432-8534 between 9 am and 4 pm EST, Monday–Friday.**

**PRINCIPAL DISPLAY PANEL**

 NuCare Pharmaceuticals, Inc.



Take \_\_\_\_\_ teaspoonful(s)  
every \_\_\_\_\_ hours  
times a day.

Manufactured by:  
Actavis Mid Atlantic LLC, Lincolnton, NC 28092  
Packaged by:  
NuCare Pharmaceuticals, Inc.  
Orange, CA 92867  
Call your doctor for medical advice about side effects.  
You may report side effects to FDA at 1-800-FDA-1088.  
**Patent Instructions:**



Rev. 07/09

NDC 68071-4217-4  
Lot #: 000000 Exp. Date: 00-00

Children's Ibuprofen 100mg/5mL  
4oz Oral Susp.

See manufacturer's label  
for full list of ingredients.

Product #: R0282004

Children's Ibuprofen 100mg/5mL  
4oz Oral Susp. Exp Date: 00-00  
NDC 68071-4217-04 AWP:  
Mfg NDC 0472-1263-94  
Lot #: 000000 Rx # 22871371

Children's Ibuprofen 100mg/5mL  
4oz Oral Susp. Exp Date: 00-00  
NDC 68071-4217-04 AWP:  
Mfg NDC 0472-1263-94  
Lot #: 000000 Rx # 22871371

Children's Ibuprofen 100mg/5mL  
4oz Oral Susp. Exp Date: 00-00  
NDC 68071-4217-04 AWP:  
Mfg NDC 0472-1263-94  
Lot #: 000000 Rx # 22871371

Children's Ibuprofen 100mg/5mL  
4oz Oral Susp. Exp Date: 00-00  
NDC 68071-4217-04 AWP:  
Mfg NDC 0472-1263-94  
Lot #: 000000 Rx # 22871371

Rx # 22871371

WARNING: KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED TEMPERATURE 68-77°F.

## CHILDRENS IBUPROFEN

ibuprofen suspension

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-4217(NDC:0472-1263)
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
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-4217-4	120 mL in 1 BOX; Type 1: Convenience Kit of Co-Package	01/09/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074916	07/01/2008	

**Labeler** - NuCare Pharmaceuticals, Inc. (010632300)**Establishment**

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-4217)

Revised: 1/2018

NuCare Pharmaceuticals, Inc.