

CHILDRENS IBUPROFEN- ibuprofen suspension
Kesin Pharma Corporation

CHILDREN'S Ibuprofen Oral Suspension, USP

Drug Facts

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

.....Purpose

Ibuprofen 100 mg (NSAID)*.....Pain
reliever/Fever reducer

*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.
- if needed, repeat dose every **6 to 8 hours**
- do not use more than **4 times a day**

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)
under 24	under 2 years	ask a doctor
24 to 35 lbs	2 to 3 years	5 mL
36 to 47 lbs	4 to 5 years	7.5 mL
48 to 59 lbs	6 to 8 years	10 mL
60 to 71 lbs	9 to 10 years	12.5 mL
72 to 95 lbs	11 years	15 mL

*or as directed by a doctor

Other information

- **each 5 mL contains: sodium 2 mg**
- store at 20°C to 25°C (68°F to 77°F)
- CHILDREN’S Ibuprofen Oral Suspension is a white, berry flavored suspension supplied in the following oral dosage forms:

NDC 81033-019-05: 5 mL unit-dose cup

NDC 81033-019-01: Case containing 100 unit-dose cups of 5 mL each.

NDC 81033-019-10: 10 mL unit-dose cup

NDC 81033-019-02: Case containing 100 unit-dose cups of 10 mL each.

Inactive ingredients

anhydrous citric acid, artificial mixed berry flavor, glycerin, high fructose corn syrup,

hypromellose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments?

Call 1-833-537-4679

Distributed by:

Kesin Pharma Oldsmar, FL 34677

PIS-019-V01

Rev. 10/2025



Principal Display Panel

NDC: 81033-019-01

CHILDREN'S Ibuprofen Oral Suspension, USP

100 mg per 5 mL

Delivers 5 mL

Case = 100 UD Cups (Do Not Break Case)

NDC: 81033-019-01

Product Name: **CHILDREN'S Ibuprofen Oral Suspension, USP**
100 mg per 5 mL

Delivers: 5 mL Case = 100 UD Cups (Do Not Break Case)

Storage: 68°F to 77°F (20°C to 25°C)

EXP: 00-NOV-0000

LOT: K0000000

QTY: 1



(17)001100(10)K0000000(30)1



(01)00381033019017



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Kesin Pharma Corporation - Oldsmar, FL



NDC: 81033-019-02

CHILDREN'S Ibuprofen Oral Suspension, USP

200 mg per 10 mL

Delivers 10 mL

Case = 100 UD Cups (Do Not Break Case)

NDC: 81033-019-02

Product Name: **CHILDREN'S Ibuprofen Oral Suspension, USP**
200 mg per 10 mL

Delivers: 10 mL Case = 100 UD Cups (Do Not Break Case)

Storage: 68°F to 77°F (20°C to 25°C)

EXP: 00-NOV-0000 LOT: K0000000 QTY: 1



(17)001100(10)K00000000(30)1



(01)00381033019024



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Internal Use Only R.01



K0000000

CHILDRENS IBUPROFEN

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81033-019
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	

HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81033-019-01	100 in 1 CASE	11/01/2025	
1	NDC:81033-019-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:81033-019-02	100 in 1 CASE	11/01/2025	
2	NDC:81033-019-10	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	ANDA074937	04/28/2011	

Labeler - Kesin Pharma Corporation (117447816)

Establishment

Name	Address	ID/FEI	Business Operations
Kesin Pharma Corporation		117447816	label(81033-019) , pack(81033-019)

Revised: 11/2025

Kesin Pharma Corporation