

IBUPROFEN- ibuprofen suspension

Proficient Rx LP

Ibuprofen

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. 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 to 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

- **Store at 20° to 25°C (68° to 77°F)** [see USP Controlled Room Temperature].
- **do not use if carton is opened or if bottle wrap imprinted with "SEALED FOR SAFETY" is broken or missing**
- see bottom panel of carton for lot number and expiration date

Inactive ingredients

acesulfame potassium, berry flavor natural & artificial, citric acid anhydrous, glycerin, polysorbate 80, pregelatinized modified starch, purified water, sodium benzoate, sucrose, xanthan gum

Questions?

Call **1-866-923-4914**

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

*Compare to the active ingredient in Children's Motrin[®] Dye-Free Berry Flavor

NDC 71205-213-72

See New Warnings

For ages 2 to 11 years

Children's

Ibuprofen

Oral Suspension, USP

100 mg per 5 mL

Pain reliever / Fever reducer (NSAID)

Dye - Free

Alcohol Free

Lasts

up to 8 hours

Berry Flavor

4 FL OZ

(120 mL)



Scan Here



NDC 71205-213-72

Relabeled By: Proficient Rx LP
Thousand Oaks, CA 913203
71205-213-72
5**Ibuprofen 100mg/ 5mL****4 FL OZ (120 mL) Oral Suspension**Each 5ml (1tsp) contains: Ibuprofen 100 mg (NSAID)* Pain reliever/ fever reducer
*nonsteroidal anti-inflammatory drug

Dye-Free Alcohol Free Berry Flavor

Product ID: SI021372

For ages 2 to 11 years

Dist. By: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532

Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Ibuprofen 100mg/ 5mL
4 FL OZ (120 mL) Oral Suspension
Lot #:00000 SN# MASTER
NDC 71205-213-72 Exp:000000Ibuprofen 100mg/ 5mL
4 FL OZ (120 mL) Oral Suspension
Lot #:00000 SN# MASTER
NDC 71205-213-72 Exp:000000Ibuprofen 100mg/ 5mL
4 FL OZ (120 mL) Oral Suspension
Lot #:00000 SN# MASTER
NDC 71205-213-72 Exp:000000GTIN: 00371205213725
SN# MASTER
Exp: 000000
Lot #:00000**IBUPROFEN**

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71205-213(NDC:51672-2130)
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
acesulfame potassium (UNII: 23OV73Q5G9)	
anhydrous citric acid (UNII: XF417D3PSL)	
glycerin (UNII: PDC6A3C0OX)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
sodium benzoate (UNII: OJ245FE5EU)	
water (UNII: 059QF0KO0R)	
sucrose (UNII: C151H8M554)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (WHITE to OFF-WHITE)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-213-72	1 in 1 CARTON	01/01/2019	
1		120 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	ANDA209207	06/27/2017	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-213) , RELABEL(71205-213)

Revised: 7/2022

Proficient Rx LP