IBUPROFEN- ibuprofen suspension
Sun Pharmaceutical Industries, Inc.

Ibuprofen

Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen 100 mg (NSAID) [1]

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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

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

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

NDC 51672-2130-8

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

Lasts
up to 8 hours

Berry Flavor

4 FL OZ
(120 mL)

For ages 2 to 11 years

Children's

Ibuprofen

Oral Suspension, USP

100 mg per 5 mL

Pain reliever / Fever reducer (NSAID)

Lasts up to 8 hours

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Oral Suspension, USP

100 mg per 5 mL

Pain reliever / Fever reducer (NSAID)

Dye - Free

Lasts up to 8 hours

Berry Flavor

4 FL OZ

Important: Read all product information before using. Keep this box for important information. This product is intended for use in children.

Drug Facts

Active Ingredient (In each 5 mL)	Purpose
Ibuprofen 100 mg (NSAID)*	Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

Uses temporarily:

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Do not use

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(120 mL)

• right before or after heart surgery

NO VARNISH/ NO AQ
NO COPY / NO COLOR
THIS FLAP FOR LOT #
AND EXP DATE PRINT

T181C
B98.2
ENG19.59

NO VARNISH
ON THIS FLAP

NO AQ/VARNISH

Drug Facts (continued)

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Drug Facts (continued)

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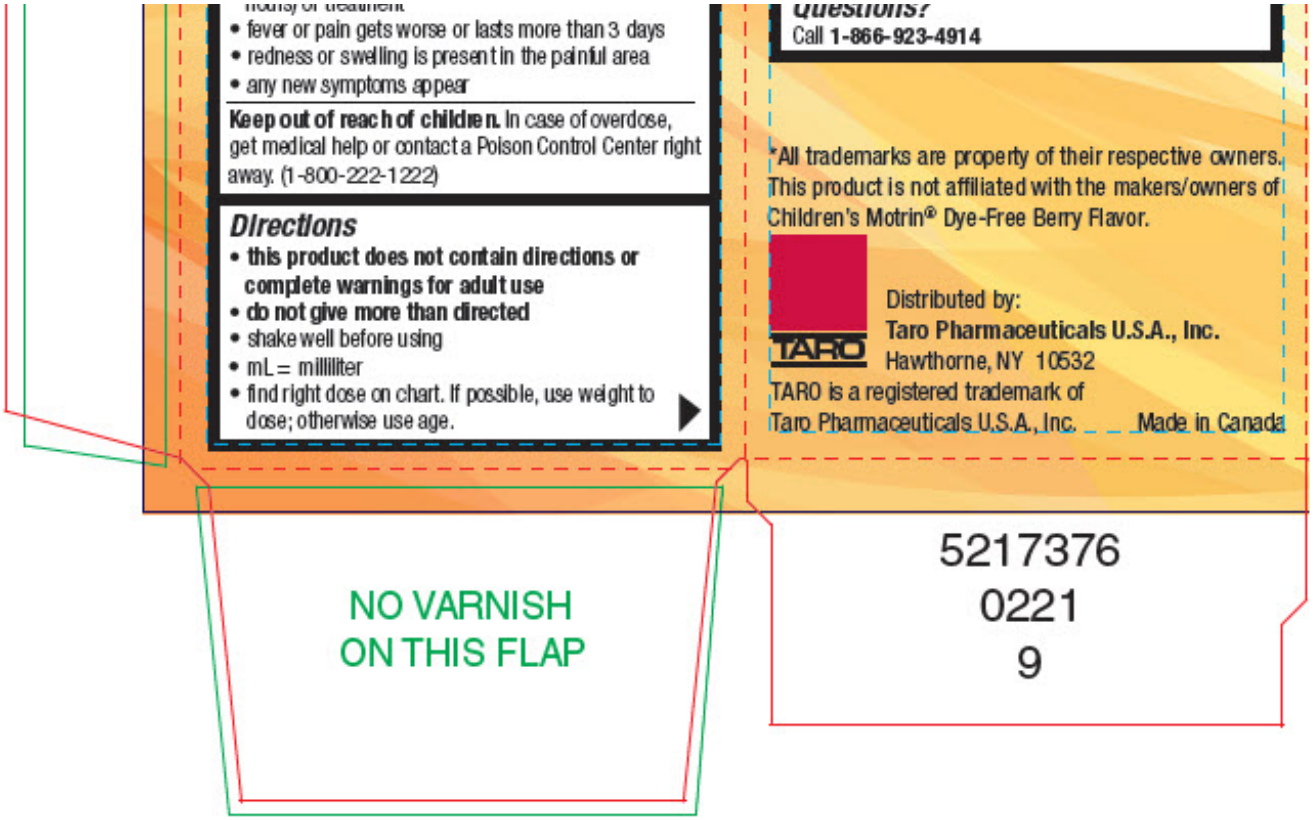
Inactive Ingredients

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

Questions?



IBUPROFEN

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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**
STARCH, CORN (UNII: O8232NY3SJ)	
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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2130-8	1 in 1 CARTON	06/27/2017	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2130-1	1 in 1 CARTON	06/27/2017	
2		240 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 - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(51672-2130)

Revised: 7/2025 Sun Pharmaceutical Industries, Inc.