

IBUPROFEN INFANTS- ibuprofen suspension/ drops
Taro Pharmaceuticals U.S.A., Inc.

Ibuprofen
Infants

Drug Facts

Active ingredient (in each 1.25 mL)

Ibuprofen 50 mg (NSAID)¹

¹ nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

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
- find right dose on chart below. If possible, use weight to dose; otherwise use age.
- mL = milliliter
- measure with the dosing device provided. Do not use with any other device.
- dispense liquid slowly into the child's mouth, toward the inner cheek
- if needed, repeat dose every **6 to 8 hours**
- do not use more than **4 times a day**

Dosing Chart

Weight (lb)	Age (mos)	Dose (mL)
under 6 mos		ask a doctor
12-17 lbs	6-11 mos	1.25 mL
18-23 lbs	12-23 mos	1.875 mL

Other information

- store between 20° to 25°C (68° to 77°F)
- **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

berry flavor natural & artificial, caramel, citric acid (anhydrous), glycerin, polysorbate 80, pregelatinized modified starch, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

Questions or comments?

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

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

*Compare to the active
ingredient in
Motrin® Infants' Drops

NDC 51672-2146-3

For Ages 6 Mos. to 23 Mos.

Concentrated

Infants' Drops
Ibuprofen

Oral Suspension (NSAID)

50 mg per 1.25 mL
Pain reliever / Fever reducer

Dye-Free
Alcohol Free

Use only with
enclosed
syringe.

Lasts
up to
8 hours

Berry Flavor

1 FL OZ (30 mL)

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)			IBUPROFEN	50 mg in 1.25 mL
Inactive Ingredients				
Ingredient Name			Strength	
CAMEL (UNII: T9D99G2B1R)				
SORBITOL SOLUTION (UNII: 8KW3E207O2)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCROSE (UNII: C151H8M554)				
WATER (UNII: 059QF0KO0R)				
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:51672-2146-3	1 in 1 CARTON	08/08/2023	
1		30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA217261		08/08/2023	

Labeler -
Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2146)