

**IBUPROFEN- ibuprofen suspension**  
**Taro Pharmaceuticals U.S.A., Inc.**

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**Ibuprofen**

***Drug Facts***

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

Ibuprofen 100 mg (NSAID) <sup>1</sup>

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<sup>1</sup> 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

<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

- **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<sup>®</sup> Dye-Free Berry Flavor

NDC 51672-2144-8

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)

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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100 mg per 5 mL

Pain reliever / Fever reducer (NSAID)

**Dye-Free**  
**Alcohol Free**

Lasts  
up to **8** hours



**Berry Flavor**

**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
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Ibuprofen 100 mg (NSAID)*....Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug	
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### 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.

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**Do not use**

Berry Flavor

4 FL OZ  
(120 mL)

- if the child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- 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

**Drug Facts** (continued)

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**Drug Facts** (continued)

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**Inactive ingredients**

ascorbic acid, potassium, berry flavor, natural 2

NO AQ/VARNISH

- 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
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**Questions?**

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\*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Children's Motrin® Dye-Free Berry Flavor.



Distributed by:  
**Taro Pharmaceuticals U.S.A., Inc.**  
Hawthorne, NY 10532

TARO is a registered trademark of Taro Pharmaceuticals U.S.A., Inc. Made in Canada

**NO VARNISH ON THIS FLAP**

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0222  
XX

**IBUPROFEN**

ibuprofen suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51672-2144
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>SUCROSE</b> (UNII: C151H8M554)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	white (WHITE to OFF-WHITE)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2144-8	1 in 1 CARTON	07/21/2022	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2144-1	1 in 1 CARTON	07/21/2022	
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	07/21/2022	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	manufacture(51672-2144)

Revised: 1/2024

Taro Pharmaceuticals U.S.A., Inc.