

**IBUPROFEN - ibuprofen suspension**  
**TARO PHARMACEUTICALS U.S.A., INC.**

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**Children's Ibuprofen Oral Suspension, USP**

**Drug Facts**

***Active ingredient***

*(in each 5 ml)*

Ibuprofen 100 mg (NSAID)\*

\*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.
- remove bottle cap and squeeze your child's dose into the dosing cup
- use only enclosed dosing cup. Do not use any other dosing device.
- if needed, repeat dose every **6-8 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

- **each 5 mL contains:**sodium 2 mg
- store between 20-25°C (68-77°F)
- **do not use if carton is opened or if carton tape or bottle wrap imprinted "SEALED FOR YOUR PROTECTION" is broken or missing**

### Inactive Ingredients

acesulfame potassium, anhydrous citric acid, glycerin, hypromellose, mix berry flavor, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

**Questions or comments**

Call 1-877-244-9825

\*All trademarks are the property of their respective owners.

Manufactured for:

**Taro Pharmaceuticals U.S.A., Inc.**

Hawthorne, NY 10532

TARO is a registered trademark of

Taro Pharmaceuticals U.S.A., Inc.

Made in India

Revised: 08/2024

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

***See New Warnings***

NDC 51672-5321-8

***For Ages 2 to 11 Years***

***Children's Ibuprofen Oral Suspension, USP (NSAID)***

***100 mg per 5 mL***

***Pain Reliever / Fever Reducer***

***Lasts up to***

***8 hours***

***Dye-Free***

***Alcohol Free***

***Berry Flavor***

***4 fl oz (120 mL)***

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)

Lasts up to  hours

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No Varnish zone

NDC-51672-5321-8

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  
Alcohol Free

Lasts up to  hours



Berry Flavor

4 FL OZ  
(120 mL)

NO VARNISH ZONE

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

**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

### Drug Facts (continued)

**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.  
• use only enclosed dosing cup. Do not use any other dosing device.  
• if needed, repeat dose every 6-8 hours

### Drug Facts (continued)

• 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
72-85 lbs	11 years	15 mL

\*or as directed by a doctor

### Other information

• each 5 mL contains: sodium 2 mg  
• store between 20-25°C (68-77°F)  
• do not use if carton is opened or if carton tape or bottle wrap imprinted "SEALED FOR YOUR PROTECTION" is broken or missing

**Inactive ingredients**  
acesulfame potassium, anhydrous citric acid, glycerin, hypromellose, mix berry flavor, polyсорtate 80, purified water, sodium benzoate, sucrose, xanthan gum

**Questions or comments?**  
Call 1-877-244-9825

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Code No.: KR/DRUGS/KTK/25/415/88

Manufactured by:  
**Taro Pharmaceuticals U.S.A., Inc.**  
Hawthorne, NY 10532  
TARO is a registered trademark of  
Taro Pharmaceuticals U.S.A., Inc.  
Made in India

1164485  
0524  
7808

No varnish zone  
Space for batch details

No Varnish zone

LOT & EXP  
to be overprinted



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

**Active ingredient (in each 5 mL):** *Ibuprofen* 100 mg (NSAID)\* .....Pain reliever/ fever reducer  
\*nonsteroidal anti-inflammatory drug

**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

For ages 2 to 11 years

NDC 51672-5321-8

# Children's Ibuprofen

## Oral Suspension, USP

100 mg per 5 mL

Pain Reliever / Fever Reducer  
(NSAID) Lasts up to **8** hoursNon-Staining • Dye-Free  
Alcohol Free • Berry Flavor **4 FL OZ (120 mL)**

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. • use only enclosed dosing cup. Do not use any other dosing device. • if needed, repeat dose every **6-8 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
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72-95 lbs	11 years	15 mL

\*or as directed by a doctor

**Other information** • each 5 mL contains: sodium 2 mg • store between 20-25°C (68-77°F) • **do not use if carton is opened or if carton tape or bottle wrap imprinted "SEALED FOR YOUR PROTECTION" is broken or missing**  
**Inactive ingredients** acesulfame potassium, anhydrous citric acid, glycerin, hypromellose, mix berry flavor, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum  
**Questions or comments?**  
Call 1-877-244-9825

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Hawthorne, NY 10532  
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Made in India 1164485 0524 5089  
Code No.: KRDRUGS/KTK/25/415/88



No varnish zone  
Space for batch details

## IBUPROFEN

ibuprofen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51672-5321
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XY10QM) (IBUPROFEN - UNII:WK2XY10QM)	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>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)

**TRIACETIN** (UNII: XHX3C3X673)

### Product Characteristics

<b>Color</b>	WHITE (Colorless)	<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:51672-5321-8	1 in 1 CARTON	08/15/2024	
1		120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:51672-5321-1	1 in 1 CARTON	10/10/2024	
2		240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211666	08/15/2024	

**Labeler** - TARO PHARMACEUTICALS U.S.A., INC. (145186370)

Revised: 3/2025

TARO PHARMACEUTICALS U.S.A., INC.