

**CHILDRENS IBUPROFEN- ibuprofen suspension**  
**Kroger Company**

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**Children's 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 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 get 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?


**1-800-632-6900**

DIST. BY THE KROGER CO., CINCINNATI, OHIO 45202

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

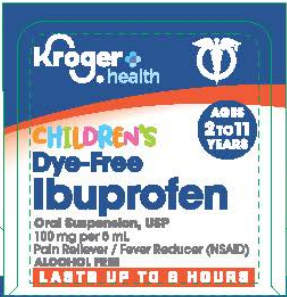
NDC 30142-965-08

Kroger®



Pharmacist Read Direction

NO VARNISH ON THIS FLAP



T181C  
B98.2  
ENG19.59

NO AQ/VARNISH

**Drug Facts (continued)**

**Ask a doctor before use if**

- stomach bleeding warning appears 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 taking 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:
  - black stool
  - 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
  - sturred 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 (1-800-222-1222) right away.**

**Directions**

- Take product dose and schedule directions or instructions warnings for adult use
- Do not give more than directed
- Shake well before using
- 1 mL = milliliter
- Find right dose on chart. If possible, use weight to dose; otherwise use age.

**Drug Facts (continued)**

- use only enclosed dosing cup. Do not use any other dosing devices.
- If needed, repeat dose every 6 to 8 hours
- do not use more than 4 doses a day
- replace original bottle cap to maintain child resistance

Weight (lb)	Age (yr)	Dose (mL)*
Under 24	Under 2 years	ask a doctor
24-35 lb	2-3 years	5 mL
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\* or as directed by a doctor

**Other Information**

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

**Inactive Ingredients**

saccharin potassium, berry flavor natural & artificial, citric acid anhydrous, glycerin, polyorbital 80, propylchloral modified starch, purified water, sodium benzoate, sucrose, xanthan gum

**Questions or comments?**  
Call 1-888-632-6600

Motrin® is a registered trademark of Kenova Inc. Proudly distributed by The Kroger Co., Cincinnati, Ohio 45202

MADE IN CANADA

For More Product Information, Scan UPC Using Your Kroger App or Call 800-632-6900

\*OUR PHARMACIST RECOMMENDED


Our Brands. Our Guarantee.  
Love It or Your Money Back.  
[www.kroger.com](http://www.kroger.com)

NO VARNISH ON THIS FLAP

5254617  
1124  
43

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

4 R. OZ.  
(120 mL)



0 41260 01288 4

**CHILDRENS IBUPROFEN**  
ibuprofen suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30142-965
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<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:30142-965-08	1 in 1 CARTON	05/14/2021	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA209207	06/27/2017	

**Labeler** - Kroger Company (006999528)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Taro Pharmaceuticals INC.		206263295	manufacture(30142-965)

Revised: 11/2024

Kroger Company