

**CHILDRENS IBUPROFEN - ibuprofen suspension/ drops**  
**Chain Drug Marketing Association Inc.**

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**Quality Choice Children's Ibuprofen Oral Suspension 572**

**ACTIVE INGREDIENT (in each 5 mL)**

Ibuprofen, USP 100 mg (NSAID)\*  
\*nonsteroidal anti-inflammatory drug

**PURPOSE**

Pain reliever/fever reducer

**USE(S)**

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
- asthma (wheezing)
- skin reddening
- facial swelling
- shock
- 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 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 the 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 **6-8 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 printed inner seal imprinted with "SEALED for YOUR PROTECTION" is broken or missing.**

## **INACTIVE INGREDIENTS**

anhydrous citric acid, FD&C red no. 40, flavor, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum.

## **PRINCIPAL DISPLAY PANEL**

**NDC 83324-013-04**

**QUALITY CHOICE**

**\* Compare to the Active Ingredient in Children's Motrin®  
Children's Ibuprofen**

**Pain Reliever/Fever Reducer**

**Oral Suspension, USP (NSAID)**

**100 mg per 5 mL**

**For Ages 2 to 11 Years**

Lasts up to 8 Hours

Alcohol Free

**Bubble Gum Flavor**

**4 FL OZ (120mL)**



**Active Ingredient** (in each 5 mL): **Ibuprofen**, USP 100 mg per 5 mL. Also contains inert ingredients. "Nonfluorinated" anti-inflammatory drug that temporarily reduces inflammation and pain due to its common cold, flu, sore throat, headache and toothache.

**Warnings:** Always take ibuprofen exactly as a nurse or doctor instructs. Do not take more than 4 doses in 24 hours. Do not take for more than 10 days unless instructed by a doctor. Do not take for more than 10 days unless instructed by a doctor. Do not take if you are allergic to ibuprofen or any of the other ingredients in this product.

CDMA, Inc. is the exclusive manufacturer of Children's Ibuprofen.

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

**Do not use if printed inner seal imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing.**

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., owner of the registered trademark **Hibinol**.

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 Nov, NJ 08575   
 www.cdmaibuprofen.com   
 Questions: 800-935-2362   
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**4 FL. OZ. (120 mL)**

**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.**

**Some breast-feeding babies or premature or low birth weight infants accompanied by high fever, headache, nausea, and vomiting may be sensitive. Check doctor promptly. Do not use more than 7 days or substitute in children under 3 years of age unless directed by a doctor.**

**Do not use if the child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer, or 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 indigestion; • child has problems or serious side effects from taking pain relievers or fever reducers; • child has not been eating foods; • child has had a lot of flat gas or vomiting or diarrhea; • child has high blood pressure, heart disease, liver problems, kidney disease or had a stroke; • child has asthma; • child is taking medicine; • child is taking medicine before use if the child is or under a doctor's care for any serious condition or taking any other drug (other than this product) at the same time as with other prescription drugs.

**Do not use and avoid a doctor if:** • child experiences any of the following signs of stomach bleeding: fainting, • vomits blood or has blood in stool, stool, or has dark, speckled stools; • child has symptoms of heart problems, such as chest pain, trouble breathing, or weakness in part or all of the body; • stomach or back swelling; • child is taking medicine that may interact with this product (24 hours) or treatment; • blood or purple pin points or hives more than 7 days; • child has trouble breathing or weakness in part or all of the body; • any new symptoms appear.

**Keep out of reach of children. Do not use in children under 18 years of age. For more information, call 1-800-235-1233.**

**Directions:** • In this product does not contain acetaminophen or complete strength for adult use. • Do not use more than directed. • Always read before using. • Do not use if the light orange cap is opened. • Do not use if the seal is broken or if the cap is damaged. • Do not use if the seal is broken or if the cap is damaged. • Do not use if the seal is broken or if the cap is damaged. • Do not use if the seal is broken or if the cap is damaged.

**NON-PRINTING AREA**

**Dosing Chart**

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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
72-83 lbs	11 years	15 mL

\* or as directed by a doctor

Other information:  
 • Each 5 mL contains sodium 2 mg.  
 • Each contains 20-21% (w/v) (80-77%).  
 • Do not use if printed inner seal imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing.  
 Inactive ingredients: antihydroxy citric acid, FDSC red no. 40, food, glucose, polyethylene glycol, propylthiouracil, purified water, sodium benzoate, sucrose, xanthan gum.

**NON-PRINTING AREA**

# CHILDRENS IBUPROFEN

ibuprofen suspension/ drops

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83324-013	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	100 mg in 5 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
WATER (UNII: 059QF0K00R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCROSE (UNII: C151H8M554)				
XANTHAN GUM (UNII: TTV12P4NEE)				
<b>Product Characteristics</b>				
<b>Color</b>		<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:83324-013-04	1 in 1 CARTON	11/10/2023	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA210149	11/10/2023		

**Labeler** - Chain Drug Marketing Association Inc. (011920774)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
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Guardian Drug Company		119210276	MANUFACTURE(83324-013)
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Revised: 11/2023

Chain Drug Marketing Association Inc.