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

Guardian Children's Ibuprofen Oral Suspension 639

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 20-25ºC (68-77ºF)

- **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, D&C yellow no. 10, FD&C red no. 40, flavor, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum

PRINCIPAL DISPLAY PANEL

NDC 83324-014-04

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

Grape Flavor
4 FL OZ (120 mL)

Active ingredient (in each 5 mL) ***Purpose***
Ibuprofen, USP 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

PEEL HERE FOR CONTINUED IMPORTANT INFORMATION

NDC 63824-014-04

"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

Grape Flavor

4 FL OZ (120 mL)

Important. Read all product information before using. Keep the 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 Motrin®.

SATISFACTION 100% GUARANTEED

Distributed by CDMA, Inc.
Novi, MI 48375
www.qualitychoice.com
Questions: 800-955-2562
MPM 53041 REV 0523

LOT:

EXP:

UNWARNISHED AREA TO REMAIN BLANK FOR LOT & EXP INFORMATION

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 a 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 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. (-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

NON-PRINTING AREA

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Other information
■ **each 5 mL contains:** sodium 2 mg
■ store between 20-25°C (68-77°F)
■ **do not use if printed inner seal imprinted with "SEALED for YOUR PROTECTION" is broken or missing.**
inactive ingredients anhydrous citric acid, D&C red no. 33, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum.

CHILDRENS IBUPROFEN

ibuprofen suspension/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83324-014
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	PURPLE	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83324-014-04	1 in 1 CARTON	11/20/2023	
1		120 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	ANDA210149	11/20/2023	

Labeler - Chain Drug Marketing Association Inc. (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(83324-014)

Revised: 11/2023 Chain Drug Marketing Association Inc.