## CHILDRENS IBUPROFEN - ibuprofen suspension/ drops Family Dollar Services, Inc.

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#### Family Wellness Childrens Ibuprofen 634

#### **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, or 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

#### OTHER INFORMATION

- each 5 mL contains: sodium 2 mg
- store between 20-25°C (68-77°F)

<sup>\*</sup>or as directed by a doctor

• 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.

#### **QUESTIONS OR COMMENTS?**

call **1-609-860-2600** (Monday-Friday 8 am - 4 pm)

PRINCIPAL DISPLAY PANEL FAMILY Wellness

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S MOTRIN®\*

Children's IBUPROFEN ORAL SUSPENSION USP 100 mg per 5 mL

Pain Reliever/Fever Reducer (NSAID)

Alcohol Free

**Mixed Berry Flavor** 

4 FL OZ (120 mL)

Active ingredient (in each 5 mL) Purpose bupralen, USP 100 mg PSARP, —Prin relevent ever reducer "resultersaid arti-frammatary drag Meet temporarile III seleves minor aches and pains due to the common cold, flu, some throat, heodache and toothache mreduces fever

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may indice: Ill hince Ill toold providing: Ill actions (wheeling)
where Ill soft-indiching Ill soft ill allergic
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The chance is higher if your child: Ill has had stomach albers ner course a migner ryan chitt. Ill has had statuch alle or bleeding problems III take a blood thining juricocapitari or stroad drug III takes other drugs containing prescription or mappeacription NSATIO (supilin, blaymain, represen, or others) III takes more or for alleng-time than directed.

PEB. HERE FOR CONTINUED IMPORTANT INFORMATION



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 missi

DISTRIBUTED BY: MIDWOOD BRANDS, LLC 510 VOLVO PKWY CHESAPEAKE, VA 23320 USA

NOT 1096 SATISFIED? Return within 30 days to the store of purchase for a refund (with receipt) or exchange.

> SKU 913183 MRV 1294 RDF 0220 100

> > RINGSHED AREA TO BE LEFT BLANK FOR LOT & EXE. INFORMATION

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Assettive Impressioners anhydrous citric acid, D&C yealow no. 10, FD&C red no. 40, flavor, paycerin, polysorbate 80, pregelatinized starch, purified water, sodium berzoate, sucrose, xanthan gurr, Questions or comments? Call 1-800-860-2800 (Monday - Friday 8 am - 4 pm)



#### **CHILDRENS IBUPROFEN**

ibuprofen suspension/ drops

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-114 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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 YELLOW NO. 10 (UNII: 35SW5USQ3G)			
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)			

Product Characteristics				
Color	ORANGE	Score		
Shape		Size		
Flavor	BERRY (Mixed Berry)	Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55319-114- 03	1 in 1 CARTON	03/27/2024		
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	03/27/2024		

## **Labeler -** Family Dollar Services, Inc. (024472631)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Guardian Drug Company		119210276	MANUFACTURE(55319-114)	

Revised: 3/2024 Family Dollar Services, Inc.