

**CHILDRENS IBUPROFEN - ibuprofen suspension/ drops**  
**Discount Drug Mart, Inc**

-----  
**Children's Ibuprofen Oral Suspension**

**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 you 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.

## **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**

- **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, flavor, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum

## **QUESTIONS OR COMMENTS?**

call 1-609-860-2600 (Monday - Friday 8:00 am - 4:30 pm EST)

## **PRINCIPAL DISPLAY PANEL**

Compare to Children's Motrin<sup>®</sup> active ingredient\*

NDC 53943-682-03

DISCOUNT drug mart

FOOD FAIR

### **Dye Free**

### **Children's**

### **Ibuprofen**

Oral Suspension, USP (NSAID)

100 mg per 5 mL

Pain Reliever/Fever Reducer

- Lasts up to 8 Hours
- No Artificial Sweetener
- Alcohol Free

### **Mixed Berry Flavor**

**4 FL OZ (120 mL)**

For Ages 2 to 11 Years  
**Dye Free**  
**Children's Ibuprofen**  
 Oral Suspension, USP (NSAID)  
 100 mg per 5 mL



For Ages 2 to 11 Years  
**Dye Free**  
**Children's Ibuprofen**  
 Oral Suspension, USP (NSAID)  
 100 mg per 5 mL

**Pain Reliever/Fever Reducer**

- Lasts up to 8 Hours
- No Artificial Sweetener
- Alcohol Free



**4 FL OZ (120 mL)**  
**Mixed Berry Flavor**

MFR# 53041 REV 0620



0 93351 03195 3

Compare to Children's Motrin® active ingredient\*

**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, USP 100 mg (NSAID)\*.....Pain reliever, fever reduce  
 \*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.

**Drug Facts (continued)**

**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. (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. →

**Drug Facts (continued)**

■ 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, flavor, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum.

**Questions or comments?**  
 Call 1-809-860-2600 (Monday - Friday 8 am - 4 pm)

**Distributed by:** Drug Mart Food Fair  
 Medina, OH 44256  
 www.discount-drugmart.com

SATISFACTION GUARANTEED  
 IF DISSATISFIED, RETURN UNUSED PORTION AND PACKAGE TO STORE WHERE PURCHASED.  
 IF UNABLE TO RETURN TO STORE, SEND REASON FOR DISSATISFACTION, NAME, ADDRESS AND EMPTY PACKAGE TO: DISCOUNT DRUG MART, 211 COMMERCE DR., MEDINA, OH 44256

\*This product is not affiliated with, manufactured by, or produced by the makers or owners of Motrin®.

WestRock 11 1064909 9/20

**CHILDRENS IBUPROFEN**

ibuprofen suspension/ drops

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-682
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	100 mg	in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY (Mixed Berry)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53943-682-03	1 in 1 CARTON	02/13/2025	
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	02/13/2025	

**Labeler** - Discount Drug Mart, Inc (047741335)

## Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(53943-682)

Revised: 2/2025

Discount Drug Mart, Inc