

IBUPROFEN INFANTS DROPS - ibuprofen suspension/ drops
Discount Drug Mart, Inc

Ibuprofen Infants Drops

ACTIVE INGREDIENT (in each 1.25 mL)

Ibuprofen 50 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

USE(S)

temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

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 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
- find right dose on chart below. If possible, use weight to dose; otherwise use age.
- mL=milliliter
- measure with dosing device provided. Do not use any other dosing device.
- dispense liquid slowly into the child's mouth, toward the inner cheek
- if needed, repeat dose every **6-8 hours**
- do not use more than **4 times a day**

Dosing Chart

WEIGHT (lb)	AGE (mos)	DOSE (mL)
under 6 mos		ask a doctor
12-17 lbs	6-11 mos	1.25 mL
18-23 lbs	12-23 years	1.875 mL

OTHER INFORMATION

- store between 20-25°C (68-77°F)
- **do not use if carton is opened or if printed neckband is imprinted with "SEALED FOR YOUR PROTECTION" and "USE WITH ENCLOSED DOSING DEVICE ONLY" is broken or missing.**

INACTIVE INGREDIENTS

anhydrous citric acid, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sorbitol, 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 Concentrated Motrin[®] Infants' Drops active ingredient*

See New Warnings

NDC 53943-637-09

Discount drug mart

FOOD FAIR

For Ages 6 mos. to 23 mos.

Concentrated Infants' Drops
IBUPROFEN

Oral Suspension, 50 mg per 1.25 mL

Pain Reliever /Fever Reducer (**NSAID**)

Lasts Up to

8 Hours

Dye-Free

Use Only With Enclosed Syringe

1 fl oz (30 mL) **Berry Flavor**

Drug Facts (continued)

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

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 ■ 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:
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 ■ weakness in one part or side of the body
 ■ slurred speech ■ leg swelling

Drug Facts (continued)

■ the child does not get any relief within first day (24 hours) of treatment
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Inactive ingredients

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Drug Facts

Active ingredient (in each 1.25 mL): Ibuprofen 50 mg (NSAID).
Purpose: Pain reliever/fever reducer

Uses: Temporarily ■ reduces fever ■ relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

Warnings: Temporarily ■ reduces fever ■ relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

See New Warnings

Compare to Concentrated Motrin® Infants' Drops active ingredients*



For Ages 6 mos. to 23 mos.

Concentrated Infants' Drops

IBUPROFEN

Oral Suspension, 50 mg per 1.25 mL

Pain Reliever/Fever Reducer (NSAID)

Use only with enclosed syringe

Lasts up to 8 Hours

Dye Free

1 fl oz (30 mL) **Berry Flavor**



LOT:

EXP:

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

SATISFACTION GUARANTEED

■ DISSATISFIED, RETURN UNUSED PORTION AND PACKAGE TO STORE WHERE PURCHASED.
 ■ 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®.



Actual Size



WestRock
 10
 1064909
 9/20

OPEN to read all Warnings and Directions before use

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Concentrated Infants' Drops
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 Pain Reliever/Fever Reducer (NSAID)
 Dye-Free Berry Flavor
 1 fl oz (30 mL)

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MFR# 53041 REV 0620

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FRONT COVER

PAGE 12

THE DOSING CHART AND DIRECTIONS APPEARING ON THE FIRST AND LAST PAGE ARE REPEATED FOR YOUR CONVENIENCE. PLEASE READ AND KEEP ALL WARNINGS AND DIRECTIONS TO ENSURE THE PROPER USE OF THIS CONCENTRATED INFANTS' IBUPROFEN PRODUCT.

Important: Read all product information before using. Keep the box for important information. This product is intended for use in children ages 6 months to 23 months of age.

Active ingredient (in each 1.25 mL) Purpose
 Ibuprofen 50 mg (NSAID)*.....Pain reliever/
 *nonsteroidal anti-inflammatory drug fever reducer

Uses temporarily:
 ■ reduces fever
 ■ relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

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DISCOUNT
drug mart
 FOOD FAIR

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Inactive ingredients anhydrous citric acid, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum.

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IBUPROFEN INFANTS DROPS

ibuprofen suspension/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-637
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	50 mg in 1.25 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53943-637-09	1 in 1 CARTON	02/13/2025	
1		30 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	ANDA210755	02/13/2025	

Labeler - Discount Drug Mart, Inc (047741335)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(53943-637)

Revised: 2/2025

Discount Drug Mart, Inc