# PARENTS CHOICE INFANTS IBUPROFEN- ibuprofen suspension/ drops Wal-Mart Stores Inc

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## Wal-Mart Infant's Ibuprofen Drug Facts

## Active ingredient (in each 1.25 mL)

Ibuprofen 50 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

## **Purposes**

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**

**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.

### 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

· give 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 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 the dosing device provided. Do not use with any other 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 (lbs)	Age (mos)	Dose (mL)	
under 6 mos		ask a doctor	
12-17 lbs	6-11 mos	1.25 mL	
18-23 lbs	12-23 mos	1.875 mL	

#### Other information

- store at 20-25°C (68-77°F)
- do not freeze
- do not use if printed neckband is broken or missing

## **Inactive ingredients**

anhydrous citric acid, glycerin, hypromellose, natural and artificial berry flavor, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

### Questions or comments?

1-877-307-2192

## **Principal Display Panel**

SEE NEW WARNINGS

Parent's CHOICE<sup>™</sup>

Age 6 to 23 Mos

Infants' Ibuprofen Concentrated Drops

Ibuprofen Oral Suspension, 50mg per 1.25mL

Pain Reliever/Fever Reducer (NSAID)

Lasts Up to 8 Hours

Non-Staining

High Fructose Corn Syrup Free

Gluten-Free

Use Only with Enclosed Syringe

COMPARE TO MOTRIN® INFANTS' DROPS BERRY FLAVOR ACTIVE INGREDIENT

Dye Free

Berry Flavor

1 FL OZ (30mL)



You'll love this Parent's Choice product, In fact, we guarantee it. If you (or your baby) aren't completely happy, please return the product to us and we'll replace it or refund your money. Your opinion means a lot to us, so if you'd like to talk, call us at 1-877-307-2192.

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Ibuprofen

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

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#### Drug Facts (continued)

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- disease, or had a stroke

   child has asthma child is taking a diuretic
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#### Drug Facts (continued)

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- do not use more than 4 times a day Dosing Chart

#### Weight (lbs) Age (mos) Dose (mL) under 6 mos ask a doctor 12-17 lbs 6-11 mos 1.25 mL 18-23 lbs 12-23 mos 1.875 mL

#### Other information

- store at 20-25°C (68-77°F)
- do not freeze do not use if printed neckband is broken or missing

Inactive ingredients anhydrous citric acid, glycerin, hypromellose, natural and artificial berry flavor, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

1-877-307-2192

#### DISTRIBUTED BY: Wal-Mart Stores, Inc., Bentonville, AR 72716

\*\*This product is not manufactured or distributed by Johnson & Johnson, owner of the register trademark Motrin®.

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COMPARE TO

MOTRIN® INFANTS' DROPS BERRY FLAVOR ACTIVE INGREDIENT\*\*

1 FL OZ (30mL)





## PARENTS CHOICE INFANTS IBUPROFEN

ibuprofen suspension/ drops

Dye Free

Berry

#### **Product Information Product Type HUMAN OTC DRUG** Item Code (Source) NDC:49035-601 **Route of Administration** ORAL

#### **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SUCROSE (UNII: C151H8M554)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics		
Color	WHITE (Opaque)	Score
Shape		Size
Flavor	BERRY (mixed)	Imprint Code
Contains		

	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:49035-601-	1 in 1 CARTON	07/12/2017			
1	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	ANDA075217	07/12/2017			

## Labeler - Wal-Mart Stores Inc (051957769)

Revised: 11/2022 Wal-Mart Stores Inc