

**CONCENTRATED IBUPROFEN INFANTS - ibuprofen suspension/ drops**  
**Chain Drug Marketing Association Inc.**

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**Quality Choice Concentrated Ibuprofen Infants Drops**

**ACTIVE INGREDIENT (in each 1.25 mL)**

Ibuprofen, USP 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 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 mos	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.

## PRINCIPAL DISPLAY PANEL

NDC 83324-005-30

**QUALITY CHOICE**

**\*Compare to the Active Ingredient in Infant's Motrin®  
 Infants' Ibuprofen  
 Concentrated Drops  
 Pain Reliever/Fever Reducer  
 Oral Suspension, (NSAID)**

**50 mg Per 1.25 mL  
 For Ages 6 to 23 Months  
 Lasts up to 8 Hours**

Alcohol Free

Dye-Free

Use only with enclosed syringe

Mixed Berry Flavor

1 fl oz (30 mL)



# CONCENTRATED IBUPROFEN INFANTS

ibuprofen suspension/ drops

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83324-005
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>STARCH, 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)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Product Characteristics

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

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:83324-005-30	1 in 1 CARTON	11/03/2023	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA210755	11/03/2023	

Revised: 11/2023

Chain Drug Marketing Association Inc.