

CONCENTRATED IBUPROFEN INFANTS - ibuprofen suspension/ drops
Guardian Drug Company

Guardian 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 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 am - 4 pm)

PRINCIPAL DISPLAY PANEL

NDC 53041-637-09

See New Warnings

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

Berry Flavor

1 fl oz (30 mL)

GUARDIAN

Drug Facts

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

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

Nonsteroidal anti-inflammatory drug

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.

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

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
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- takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
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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 a 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 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

Drug Facts (continued)

- 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

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- 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 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

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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 am - 4 pm)

See New Warnings NDC 53041-637-09

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

Berry Flavor

Use only with enclosed syringe

1 fl oz (30 mL) **GUARDIAN**

Manufactured by:
Guardian Drug Company
 2 Charles Court
 Dayton, New Jersey 08810 USA

NDC 53041-637-09

Concentrated Infants' Drops

IBUPROFEN

Oral Suspension
50 mg per 1.25 mL

Pain Reliever/Fever Reducer (NSAID)

Dye-free Berry Flavor

1 fl oz (30 mL) **GUARDIAN**

Actual Size



LOT:

EXP:

CONCENTRATED IBUPROFEN INFANTS
 ibuprofen suspension/ drops

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53041-637
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:53041-637-09	1 in 1 CARTON	10/03/2018	
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	10/03/2018		

Labeler - Guardian Drug Company (119210276)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(53041-637)