IBUPROFEN INFANTS DROPS - ibuprofen suspension/ drops Harris Teeter, LLC

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 8:00 am - 4:30 pm EST)

PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in Motrin® Infants' Drops Dye-Free*

Harris Teeter™

NDC 69256-687-09

For Ages 6 mos. to 23 mos.
Infants' Concentrated Drops
Ibuprofen
Oral Suspension
50 mg per 1.25 mL
PAIN RELIEVER/FEVERREDUCER (NSAID)

Dye-Free

- Lasts up to 8 Hours
- Use Only With Enclosed Syringe
- Non-Staining

Berry Flavor

1 FL OZ (30 mL)

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 # askin reddening # rash # blisters

If an allergic reaction occurs, stop use and seek medical help

which may cause severe stomach bleeding. The chance is higher if your child:

- nigher if your child:

 I has had stomach ulcers or bleeding problems

 I takes a blood thinning (anticoagulant) or steroid drug

 I takes other drugs containing prescription or nonprescription

 NSADO signifin, buprofen, naproxen, or others)

 I 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.

Grected 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

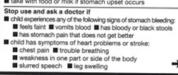
- stomach bleeding warning applies to your child
 child has a history of stomach problems, such as heartbu
 child has problems or serious side effects from taking
 pain relievers or fever reducers
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
 child 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 conditi ■ taking any other drug

When using this product

take with food or milk if stomach upset occurs



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 appea

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.
- 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

WEIGHT (Ib)	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 imprinted with "SEALED FOR YOUR PROTECTION" and "USE WITH ENCLOSED DOSING DEVICE ONLY" is broken or missing

Inactive ingredients anhydrous citric id, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sorbitol, sucrose,

Questions or comments?

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

cold, flu, sore throat, headaches and toothaches normmor aches and pains due to the common US65 temporarily: In reduces fever

esodind

"(CLAZV) gm 0č netorquo Active ingredient (in each 1.25 mL)

Drug Facts

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



For Ages 6 Mos. to 23 Mos. Infants' Concentrated Drops lbuproten Oral Suspension

50 mg per 1.25 mL

PAIN RELIEVER/ FEVER REDUCER (NSAID)

Dye-Free

- Lasts up to 8 Hours
- Use Only With Enclosed Syringe
- Non-Staining



* This product is not manufactured or distributed by

Johnson & Johnson Consumer Inc., owner of the

PROUDLY DISTRIBUTED BY: HARRIS TEETER, LLC MATTHEWS, NC 28105

> 1-800-432-6111 or harristeeter.com



For Ages 6 Mos. to 23 Mos. Infants' Concentrated Drops

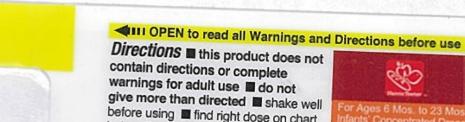
Ibuprofen

Oral Suspension 50 mg per 1.25 mL

- PAIN RELIEVER/ FEVER REDUCER (NSAID) · Lasts up to 8 Hours · Non-Staining Use Only With Enclosed Syringe
 - Berry Flavor 1 FL OZ (30 mL)

Actual Size





give more than directed ■ shake well before using I 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



PAIN RELIEVER/ FEVER REDUCER (NSAID)

- · Lasts up to 8 Hours · Non-Staining
- Use Only With Enclosed Syringe Berry Flavor

1 FL 07 (30 ml)

Weight (IL)		• 1 L OZ (30 ML)	
Weight (lb)	Age (mos)	Dose (mL)	
under	under 6 mos		
12-17 lbs	6-11 mos	ask a doctor 1.25 mL	
18-23 lbs	12-23 mos	1.875 ml	
		1.075 [11]	

IBUPROFEN INFANTS DROPS

ibuprofen suspension/ drops

Product Information

Product Type NDC:69256-687 HUMAN OTC DRUG Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
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:69256-687- 09	1 in 1 CARTON	01/29/2025	
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	01/29/2025	

Labeler - Harris Teeter, LLC (048463103)

Revised: 2/2025 Harris Teeter, LLC