IBUPROFEN- ibuprofen suspension
Central Texas Community Health Centers

Ibuprofen

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

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 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, or kidney disease
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- 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.

- 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
- see bottom of box for lot number and expiration date

Inactive ingredients

anhydrous citric acid, FD&C red #40, glycerin, hypromellose, natural and artificial berry flavor, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Label

CommUnityCare Federally Qualified Health Centers

IBUPROFEN
INFANT
DROPS

Date:

Name:
Dr.

USE AS DIRECTED

123456

1/1/01

IBUPROFEN INFANT Drops NDC 76413-312-15

Batch: 123456
Lot: 123456
Exp: 1/1/01

SUMARK

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed

CommUnityCare Federally Qualified Health Centers

IBUPROFEN
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USE AS DIRECTED

TOME COMO INDICADO

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Batch: 123456 Lot: 123456 Exp: 1/1/01 SUMARK

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IBUPROFEN

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76413-312(NDC:49348-374)
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
Xanthan Gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	PINK (light)	**Score**	
Shape		**Size**	
Flavor	FRUIT (mixed)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-312-15	1 in 1 CARTON	08/28/2003	
1		15 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	08/28/2003	

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-312) , RELABEL(76413-312)

Revised: 4/2017 Central Texas Community Health Centers