IBUPROFEN- ibuprofen suspension CVS Pharmacy

CVS Pharmacy, Inc. Ibuprofen Oral Suspension Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

temporarily:

- relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache
- reduces fever

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 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
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed dosing cup. Do not use any other dosing device.
- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance
- wash dosage cup after each use

Weight (lb)	Age (yr)	Dose (mL)**	
under 24 lbs	under 2 years	ask a doctor	
24-35 lbs	2-3 years	5 mL	
36-47 lbs	4-5 years	7.5 mL	
48-59 lbs	6-8 years	10 mL	
60-71 lbs	9-10 years	12.5 mL	
72-95 lbs	11 years	15 mL	

** or as directed by a doctor

Other information

- each 5 mL contains: sodium 2 mg
- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)

Dosing Chart

• do not freeze

Inactive ingredients

anhydrous citric acid, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, natural and artificial bubblegum flavors, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments?

1-800-719-9260

Principal Display Panel

CVS Health[®] Compare to the active ingredient in Children's Motrin[®] Suspension Liquid For Ages 2 to 11 Years Children's Ibuprofen Oral Suspension 100 mg per 5 mL Pain reliever; Fever reducer (NSAID) Gluten free Alcohol free SEE NEW WARNINGS LASTS UP TO 8 HOURS Bubble Gum Flavor 4 FL OZ (120 mL)



Pain reliever; Fever reducer (NSAID) Fever reducer (NSAID)

For ages 2 to 11 Years Children's

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Drug Facts (continued)

- 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
- mL = milliliter; tsp = teaspoonful
 find right dose on chart. If possible, use
- weight to dose; otherwise use age. ■ use only enclosed dosing cup. Do not use any other dosing device.
- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance
- wash dosage cup after each use

Drug Facts (continued)

Dosing Chart				
Weight (lb)	Age (yr)	Dose (mL or tsp)**		
under 24 lbs	under 2 years	ask a doctor		
24-35 lbs	2-3 years	5 mL (1 tsp)		
36-47 lbs	4-5 years	7.5 mL (1½ tsp)		
48-59 lbs	6-8 years	10 mL (2 tsp)		
60-71 lbs	9-10 years	12.5 mL (21/2 tsp)		
72-95 lbs	11 years	15 mL (3 tsp)		
**or as directed by a doctor				

Other information

- each 5 mL (1 tsp) contains: sodium 2 mg
 do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- do not freeze
- see bottom panel for lot number and expiration date

Inactive ingredients anhydrous citric acid, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, natural and artificial bubblegum flavors, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments? 1-800-719-9260

[†]This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin[®].

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LOT NO.	

EXP.

: 16656 17 CA

IBUPROFEN					
buprofen suspension					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:59779-166	
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingred	ient Name		Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XYI10QM)	(IBUPROFEN - UNII:WK2XYI10	QM)	IBUPROFEN	100 mg in 5 mL	
	In a ve die at Newse				
Inactive Ingredients					
	Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII:	-			Strength	
	XF417D3PSL)			Strength	
FD&C RED NO. 40 (UNII: WZB91)	XF417D3PSL)			Strength	
FD&C RED NO. 40 (UNII: WZB91: GLYCERIN (UNII: PDC6A3C0OX)	XF417D3PSL) 27XOA)			Strength	
FD&C RED NO. 40 (UNII: WZB91: GLYCERIN (UNII: PDC6A3C0OX) HIGH FRUCTOSE CORN SYRUP	XF417D3PSL) 27XOA) (UNII: XY6UN3QB6S)			Strength	
FD&C RED NO. 40 (UNII: WZB91: GLYCERIN (UNII: PDC6A3C0OX) HIGH FRUCTOSE CORN SYRUP HYPROMELLOSE, UNSPECIFIED	XF417D3PSL) 27XOA) (UNII: XY6UN3QB6S) (UNII: 3NXW29V3WO)			Strength	
FD&C RED NO. 40 (UNII: WZB91: GLYCERIN (UNII: PDC6A3C0OX) HIGH FRUCTOSE CORN SYRUP HYPROMELLOSE, UNSPECIFIED POLYSORBATE 80 (UNII: 60ZP39	XF417D3PSL) 27XOA) (UNII: XY6UN3QB6S) (UNII: 3NXW29V3WO)			Strength	
FD&C RED NO. 40 (UNII: WZB91: GLYCERIN (UNII: PDC6A3C0OX) HIGH FRUCTOSE CORN SYRUP HYPROMELLOSE, UNSPECIFIED POLYSORBATE 80 (UNII: 60ZP39 WATER (UNII: 059QF0K00R)	XF417D3PSL) 27XOA) (UNII: XY6UN3QB6S) (UNII: 3NXW29V3WO) 0ZG8H)			Strength	
FD&C RED NO. 40 (UNII: WZ B913 GLYCERIN (UNII: PDC6A3C0OX) HIGH FRUCTOSE CORN SYRUP HYPROMELLOSE, UNSPECIFIED POLYSORBATE 80 (UNII: 60Z P33 WATER (UNII: 059QF0K00R) SODIUM BENZOATE (UNII: 0J245	XF417D3PSL) 27XOA) (UNII: XY6UN3QB6S) (UNII: 3NXW29V3WO) 0ZG8H)			Strength	
HIGH FRUCTOSE CORN SYRUP HYPROMELLOSE, UNSPECIFIED	XF417D3PSL) 27XOA) (UNII: XY6UN3QB6S) (UNII: 3NXW29V3WO) 0ZG8H) FE5EU)			Strength	
FD&C RED NO. 40 (UNII: WZ B91: GLYCERIN (UNII: PDC6A3C0OX) HIGH FRUCTOSE CORN SYRUP HYPROMELLOSE, UNSPECIFIED POLYSORBATE 80 (UNII: 6OZP39 WATER (UNII: 059QF0K00R) SODIUM BENZOATE (UNII: 0J245 SORBITOL (UNII: 506T60A25R)	XF417D3PSL) 27XOA) (UNII: XY6UN3QB6S) (UNII: 3NXW29V3WO) 0ZG8H) FE5EU)			Strength	
FD&C RED NO. 40 (UNII: WZ B91: GLYCERIN (UNII: PDC6A3C0OX) HIGH FRUCTOSE CORN SYRUP HYPROMELLOSE, UNSPECIFIED POLYSORBATE 80 (UNII: 6OZP39 WATER (UNII: 059QF0K00R) SODIUM BENZOATE (UNII: 0J245 SORBITOL (UNII: 506T60A25R) XANTHAN GUM (UNII: TTV12P4NE Product Characteristics	XF417D3PSL) 27XOA) (UNII: XY6UN3QB6S) (UNII: 3NXW29V3WO) 0ZG8H) FE5EU)	Score	2	Strength	

Fla	avor		BUBBLE GUM	Imprint Code		
Co	ontains					
Pa	ackaging					
#	ltem Code		Package Description		ng Start ate	Marketing End Date
L	NDC:59779-166- 26	1 in 1 CAF	TON	08/27/2002		
1		120 mL in Product	1 BOTTLE; Type 0: Not a Comb	ination		
2	NDC:59779-166- 34	1 in 1 CAF	TON	04/09/2008		
2		240 mL in Product	1 BOTTLE; Type 0: Not a Comb	ination		
3	NDC:59779-166- 28	1 in 1 CAF	TON	09/08/2015		01/31/2020
3		148 mL in Product	1 BOTTLE; Type 0: Not a Comb	ination		
Μ	larketing	Inforn	nation			
	Marketing Category		lication Number or Monog Citation		ing Start ate	Marketing End Date
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Labeler - CVS Pharmacy (062312574)

Revised: 12/2022

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