

INFANTS ADVIL- ibuprofen suspension/ drops
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Drug Facts

Active ingredient (in each 1.25 mL)

Ibuprofen 50 mg (NSAID)¹

1 nonsteroidal anti-inflammatory drug

Purpose

Fever reducer/Pain reliever

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, 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 the 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.

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 the child
- child has problems or serious side effects from taking pain relievers or fever reducers
- child has a history of stomach problems, such as heartburn
- child has high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
- 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
- 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.

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.
- repeat dose every **6-8 hours**, if needed
- do not use more than **4 times a day**
- measure with the dosing device provided. Do not use with any other device.

Dosing Chart

Weight (lb)	Age (mos)	Dose (mL)
under 6 mos		ask a doctor
12-17 lb	6-11 mos	1.25 mL
18-23 lb	12-23 mos	1.875 mL

Other Information

- one dose lasts 6-8 hours
- store at 20-25°C (68-77°F)
- see bottom of box for lot number and expiration date

Inactive ingredients

acetic acid, artificial flavor, butylated hydroxytoluene, carboxymethylcellulose sodium, citric acid monohydrate, edetate disodium, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

Questions or comments?

Call toll-free **1-800-88-ADVIL** or ask your pharmacist, doctor or health care professional

For most recent product information, visit www.Advil.com.

PRINCIPAL DISPLAY PANEL

Infants'

Advil®

Concentrated Drops

Ibuprofen Oral Suspension

50 mg per 1.25 mL

Pain Reliever/Fever Reducer (NSAID)

Fever

Aches & Pains

Lasts Up To

8

Hours

Dye-Free

**White Grape Flavored Drops
for ages 6-23 months**

1/2 FL OZ (15 mL)

Alcohol-Free



INFANTS ADVIL

ibuprofen suspension/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-0191
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
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ACETIC ACID (UNII: Q40Q9N063P)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (Translucent off-white)	Score	
Shape		Size	
Flavor	GRAPE (White grape)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0191-20	1 in 1 CARTON	01/30/1998	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:0573-0191-50	1 in 1 CARTON	01/30/1998	
2		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:0573-0191-22	1 in 1 CARTON	01/30/2014	
3		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
4	NDC:0573-0191-75	1 in 1 CARTON	01/30/1998	
4		22.5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020812	01/30/1998	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Establishment			
Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0573-0191) , LABEL(0573-0191) , MANUFACTURE(0573-0191) , PACK(0573-0191)

Revised: 3/2023

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC