IBUPROFEN- ibuprofen suspension
ATLANTIC BIOLOGICALS CORP.

Major Pharmaceuticals Children's Ibuprofen Oral Suspension Drug Facts

Active ingredient (in each 5 mL = 1 teaspoonful)

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

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
- 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

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 (2½ 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, artificial mixed berry flavor, D&C yellow #10, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments?

1-800-719-9260

IBUPROFEN SUSPENSION

IBUPROFEN

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-5309(NDC:0904-5309)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	ORANGE	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-5309-1	5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	01/28/2021	
2	NDC:17856-5309-2	10 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	09/20/2019	09/20/2019
3	NDC:17856-5309-3	1 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	09/20/2019	09/20/2019
4	NDC:17856-5309-4	20 mL in 1 CUP; Type 0: Not a Combination Product	01/28/2021	
5	NDC:17856-5309-5	5 mL in 1 CUP; Type 0: Not a Combination Product	01/28/2021	
6	NDC:17856-5309-6	15 mL in 1 CUP; Type 0: Not a Combination Product	01/28/2021	
7	NDC:17856-5309-7	7.5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	01/28/2021	
8	NDC:17856-5309-9	1 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	01/28/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074937	02/07/1999	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	REPACK(17856-5309)

Revised: 12/2023 ATLANTIC BIOLOGICALS CORP.