

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

17856-5309-01
CHILDREN'S IBUPROFEN
ORAL SUSPENSION
100 mg PER 5 mL
DELIVERS 100mg/5mL



See package insert for indications and dosage schedule

Berry Flavored Pain Reliever. Alcohol Free Fever Reducer. Gluten Free. Shake Well before Using. Each 5mL contains Sodium 2mg. Do NOT Freeze. Store at 20°-25°C(68°-77°F).
****Keep this and all Medications out of the reach of children****



17856-5309-01 Dosage 100mg/5mL

CHILDREN'S IBUPROFEN
ORAL SUSPENSION

Qty: 48 Syringes



GTIN: 00317856530910
S/N: XXXXXXXXXXXX
Exp: 11/08/24
Lot: XXXXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-5309-04
CHILDREN'S IBUPROFEN
ORAL SUSPENSION
100 mg PER 5 mL
DELIVERS 400mg/20mL



See package insert for indications and dosage schedule

Berry Flavored Pain Reliever. Alcohol Free Fever Reducer. Gluten Free. Shake Well before Using. Each 5mL contains Sodium 2mg. Do NOT Freeze. Store at 20°-25°C(68°-77°F).
****Keep this and all Medications out of the reach of children****



17856-5309-04 Dosage 400mg/20 mL

CHILDREN'S IBUPROFEN Qty: 50 Cups
ORAL SUSPENSION



GTIN: 00317856530941
S/N: XXXXXXXXXXXX
Exp: 11/08/24
Lot: XXXXXXXXXXXX



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Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-5309-05
CHILDREN'S IBUPROFEN
ORAL SUSPENSION
100 mg PER 5 mL
DELIVERS 100mg/5mL



See package insert for indications and dosage schedule

Berry Flavored Pain Reliever. Alcohol Free Fever Reducer. Gluten Free. Shake Well before Using. Each 5mL contains Sodium 2mg. Do NOT Freeze. Store at 20°-25°C(68°-77°F).
****Keep this and all Medications out of the reach of children****



217856530905

17856-5309-05 Dosage 100 mg/5 mL

CHILDREN'S IBUPROFEN
ORAL SUSPENSION

Qty: 72 Cups



GTIN: 00317856530958

S/N: XXXXXXXXXXXX

Exp: 11/08/24

Lot: XXXXXXXXXXXX



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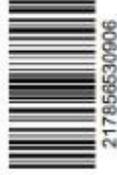
Call to Reorder:

17856-5309-06
CHILDREN'S IBUPROFEN
ORAL SUSPENSION
100 mg PER 5 mL
DELIVERS 300mg/15mL



See package insert for indications and dosage schedule

Berry Flavored Pain Reliever. Alcohol Free Fever Reducer. Gluten Free. Shake Well before Using. Each 5mL contains Sodium 2mg. Do NOT Freeze. Store at 20°-25°C(68°-77°F).
****Keep this and all Medications out of the reach of children****



17856-5309-06 Dosage 300 mg/15 mL

CHILDREN'S IBUPROFEN
ORAL SUSPENSION **Qty: 72 Cups**



GTIN: 00317856530965
S/N: XXXXXXXXXXXX
Exp: 11/08/24
Lot: XXXXXXXXXXXX



Packaged by:

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Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-5309-07
CHILDREN'S IBUPROFEN
ORAL SUSPENSION
100 mg PER 5 mL
DELIVERS 150mg/7.5mL



See package insert for indications and dosage schedule

Berry Flavored Pain Reliever. Alcohol Free Fever Reducer. Gluten Free. Shake Well before Using. Each 5mL contains Sodium 2mg. Do NOT Freeze. Store at 20°-25°C(68°-77°F).
****Keep this and all Medications out of the reach of children****



217856530907

17856-5309-07 Dosage 150 mg/7.5 mL

CHILDREN'S IBUPROFEN Qty: 72 Cups
ORAL SUSPENSION



GTIN: 00317856530972
S/N: XXXXXXXXXXXX
Exp: 11/08/24
Lot: XXXXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-5309-08
CHILDREN'S IBUPROFEN
ORAL SUSPENSION
100 mg OER 5 mL
DELIVERS 200mg/10mL



See package insert for indications and dosage schedule

Berry Flavor Pain Reliever, Alcohol Free Fever Reducer. Gluten Free. Shake Well before using. Each 5 mL contains Sodium 2 mg. Do NOT Freeze. Store at 20°-25°C (68°-77°F)
****Keep this and all medications out of the reach of children****



17856-5309-08 Dosage 200mg/10mL

CHILDREN'S IBUPROFEN Qty: 72 CUPS
ORAL SUSPENSION



GTIN: 00317856530989
 S/N: XXXXXXXXXXXX
 Exp: 04/01/25
 Lot: XXXXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp,
 Miami, FL 33179

Rev.08/21

Call to Reorder:

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
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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	
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	01/28/2021
9	NDC:17856-5309-8	72 in 1 CASE	04/02/2025	
9		10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

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)