

KOSHER MEDS- ibuprofen suspension
Mollec Inc

KOSHER-MEDS Children's Ibuprofen

Active Ingredient

Ibuprofen 100mg (NSAID)

Purpose

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 ibuprofen or 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

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 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

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	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

Inactive ingredients

Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

Questions or comments?

Call 1-732-314-4550 from 9 AM to 5 PM EST, Monday-Friday.

Product label

Important: Read all product information before using. Keep the box for important information. This product is intended for use in children.

Drug Facts

Active ingredient (in each 5 mL) **Purpose**
Ibuprofen 100 mg (NSAID)*..... Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

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 ibuprofen or 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** ■ 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 body ■ slurred speech ■ leg swelling ■ the child



Lot/Exp Date

PEEL HERE

Hinge

Drug Facts (continued)

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 below. 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

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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 ■ store between 20-25° C (68-77° F) ■ do not use if printed neckband is broken or missing

Inactive ingredients Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose and xanthan gum

Questions or Comments?

Call weekdays from 9:30 AM to 4:30 PM EST at 1-732-314-4550

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

Distributed by:
kosher-meds™
Monsey NY 10952 USA
www.kosher-meds.com

the first kosher certified children's ibuprofen





Drug Facts (continued)

- 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

- 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 body
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*or as directed by a doctor

Drug Facts (continued)

Other information

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

Inactive ingredients

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Distributed by: **kosher-meds™**
 Monsey NY, 10952, USA
 www.kosher-meds.com
 BX:135REV01

kosher-meds
 Children's
Ibuprofen
 the first kosher certified
 children's ibuprofen

See New Warnings NDC 82179-001-04

kosher-meds™
 WITH KOSHER GLYCERIN

compare to the active ingredient in Children's Motrin®**

Children's Ibuprofen

Oral Suspension (NSAID)
 100 mg per 5 mL

**Pain Reliever/
 Fever Reducer**

Original Berry Flavor

FOR AGES 2 TO 11 YEARS 4 fl oz (118 mL)

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Drug Facts

Active ingredient (in each 5 mL) Purpose

Ibuprofen 100 mg (NSAID)..... Pain reliever/
 nonsteroidal anti-inflammatory drug fever reducer

Uses temporarily:

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

Warnings

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- 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

KOSHER MEDS

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82179-001
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)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCROSE (UNII: C151H8M554)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82179-001-04	1 in 1 BOX	08/17/2021	
1		118 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	ANDA210602	08/17/2021	

Labeler - Mollec Inc (040088196)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(82179-001)

Revised: 11/2023

Mollec Inc