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 condtion
- 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 ctiric acid, carboxylmethylcellulose 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 Purpose (in each 5 mL)

buprofen 100 mg (NSAID)"...... Pain retiever/ nonsteroidal anti-inflammatory drug

Uses temporarily:

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

Warnings

Allergy alert: buprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ** hives ** facial swelling ** asthma (wheezing) ** shock ** skin reddening ** rash ** bilisters. 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, buprofen, 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 lbuprofen or any other pain reliever/fever reducer a right before or after heart surgery

Ask a doctor before use if a stomach bleeding warning applies to your child a child has a history of stomach problems, such as by your child = Chain less at issuery or sommer processes, such as hearthum ■ 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 verniting or diarrhou ■ child has high blood pressure, heart disease, liver crimbolis, kidney the child has high blood pressure, heart disease, liver crimbolis, 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 stemach upset occurs Stop use and ask a doctor if a child experiences any of the following signs of stomach bleeding: • feels taint • vernits 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



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 anhydrous citric acid, carboxymethylceflulose sodium, D&C contact a Poison Control Center right away, (1-800-222-1222) Yellow #10, FD&C Red #40, fisvors, glycerin, microcrystal-

warnings for adult use

do not give more than directed = shake well before using in the directed shake well before using interest of the directed shake well before using interest of the directed shake well before using interest of the directed shake well before using the directed shake well before using the directed shake well before using Questions or Comments?

dose; otherwise use age. I use only enclosed dosing cup. Do not use any other. Call weekdays from 9:30 AM to 4:30 PM EST at dosing device. ■ if needed, repeal dose every 6-8 hours ■ do not use more 1-732-314-4550 than 4 times a day ■ replace original bottle cap to maintain child resistance. This product is

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or as directed by a doctor

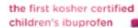
Other information ■ each 5 mL contains: sodium 2 mg = store between 20-25 °C (68-77 °F) = do not use if printed neckband is broken or missing

Inactive ingredients Acesufame potassiu Directions this product does not contain directions or complete line cellulose, polysorbale 80, propylene glycol, purified water, sodium benzoate, sucrose and xanthan gum

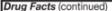
This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin®.

Distributed by: kosher-med:

Monsey NY 10952 USA







- 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:
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72-95 lbs	11 years	15 mL

Drug Facts (continued)

Other information

- Unter Information

 # each 5 m. contains; sodium 2 mg

 # store between 20-25 °C (68-77 °F)

 # do not use if carrion is opened or printed bottle neckband is broken or missing

 # see bottom panel for lot number and expiration date

Inactive ingredients

inactive intig electrics cesulfame potassium, anthydrous citric acid, arboxymethylcellulose sodium, D&C Yellow #10, FD&C ed #40, flavors, glycerin, microcrystalline cellulose, olysorbate 80, propylene glycot, purified water, sodium enzoate, sucrose, and xanthan gum

Questions or comments?

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Distributed by: kosher-meds™ Monsey NY, 10952, USA

www.kosher-meds.com



kosher-meds

children's **Ibuprofen**

ORAL

See New Warnings NDC 82179-001-04

kosher-*meds* WITH KOSHER GLYCERIN

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

Children's

Oral Suspension (NSAID) 100 mg per 5 mL

Pain Reliever/ Fever Reducer



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

ortant: Read all product information before using, Keep this box for important information. This product is intended for use in children.

Drug Facts

Active ingredient (in each 5 mL)

Ibupraten 100 mg (NSAID)".

Pain relieve nonsteroidal anti-inflammatory drug

Uses temporarily:

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reduces fever

Warnings Allergy alert: buprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- may incuos:

 | hives | facial swelling | asthma (wheezing) |
 | shock | skin reddening | rash | blisters |
 | allergic reaction occurs, stop use and seek medical
- elp right away. **Itomach bleeding warning:** This product contains an
- Stomach bleeding warning: This product contains an MSAID, which may cause severe stomach bleeding. The chance is higher if your child:

 It has had stomach ulcers or bleeding problems.

 It takes a blood thinning (enticosegularity or steroid drug takes other drugs containing prescription or nonprescription MSAIDs (aspirin, ibuprofen, naprosen, or others).

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Takes mote of the supper time start or indicated Heart attack and stroke warning: ISSADs, except asprin, increase the risk of heart attack, heart failure, and atrick. These can be fatal. The risk in higher if you use more than directed or for longer than directed. Sore throat warning: Severe or persistent ser throat or sore throat warning: Severe or persistent ser throat or sore throat warning: Severe or persistent ser throat or sore throat warning: Severe or persistent ser throat sore throat warning: Severe or persistent ser throat sore throat warning: Severe or persistent ser throat sore throat warning services. In consultation of the services of the services of warning are supplied to the services of warning are supplied to the services. years of age unless directed by doctor.

- Do not use

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- - Ask a doctor before use if
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KOSHER MEDS

ibuprofen suspension

Product Information

Route of Administration

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82179-001

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name 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: 230V73Q5G9)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SUCROSE (UNII: C151H8M554)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)			
GLYCERIN (UNII: PDC6A3C0OX)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
WATER (UNII: 059QF0KO0R)			

P	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