# **KOSHER MEDS DYE-FREE IBUPROFEN- ibuprofen suspension Mollec Inc**

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## **Kosher Meds Dye-Free Ibuprofen**

## Active ingredient (in each 5 mL)

Ibuprofen 100 mg (NSAID)\*
\*nonsteroidal anti-inflammatory drug

## **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	

<sup>\*</sup>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 carton is opened or printed bottle neckband is broken or missing
- see bottom panel for lot number and expiration date

## Inactive ingredients

Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

## Questions or comments?

#### **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 reliever/ 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 allert: Duprofen 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.



4 fl oz (118 mL) **Original Berry Flavor** 

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 flouroffen 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



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#### 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

Directions = this product does not contain directions or complete 80, propylene glycol, purified water, sodium benzoate, warnings for adult use

■ do not give more than directed ■ shake well before using
■ mL = mililiter ■ 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 Call weekdays from 9:30 AM to 4:30 PM EST at dosing device.■ if needed, repeat 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

**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

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

resent 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)

Inactive ingredients Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, flavors, glycerin, microcrystelline cellulose, polysorbate

#### Questions or Comments?

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

Distributed by: kosher-meds<sup>TI</sup> Monsey, NY 10952 USA www.kosher-meds.com

THE FIRST KOSHER CERTIFIED CHILDREN'S IBUPROFEN





## **KOSHER MEDS DYE-FREE IBUPROFEN**

ibuprofen suspension

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82179-006	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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)				

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:82179-006- 04	1 in 1 BOX	07/18/2025		
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	07/18/2025	

# **Labeler -** Mollec Inc (040088196)

Revised: 8/2025 Mollec Inc