

**CHILDRENS IBUPROFEN ORAL SUSPENSION- ibuprofen suspension**  
**Reliable 1 Laboratories LLC**

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**Drug Facts**

Ibuprofen 100 mg (NSAID) 1  
nonsteroidal anti-inflammatory drug

**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

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

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 carton is opened or printed bottle neckband is broken or missing**

## Questions or comments

Call 1-516-341-0666 9AM-5 PM EST Monday - Friday

acesulfame potassium, anhydrous citric acid, D&C yellow no. 10, FD&C red no. 40, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum

Pain reliever/fever reducer

## Principal Display Panel

NDC 69618-078-54

For Ages 2 to 11 Years

Children's Ibuprofen Oral Suspension

Oral Suspension (NSAID)

100 mg per 5 mL

Pain Reliever / Fever Reducer

Lasts up to 8 hours

Dye Free

Original Berry Flavor

4 fl oz (118 mL)

### Carton Label

NO COATING

**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
  - 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		
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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**

Acetaminophen potassium, anhydrous citric acid, carbonylmethylcellulose sodium, flavors, glycerin, microcrystalline cellulose, polyacrylate 26, propylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

**Questions or comments?**  
Call 1-518-341-0666 from 9 AM to 5 PM EST, Monday - Friday

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

Distributed by:  
Reliable-1 Labs, LLC  
89 W Hawthorne Ave Suite 610  
Valley Stream, NY 11580

BX-182

NDC 69618-078-54



**Reliable-1**  
LABORATORIES

**PAIN RELIEVER / FEVER REDUCER**  
Compare to the active ingredient in Children's Motrin®\*\*



**Children's  
Ibuprofen  
Oral Suspension**  
100 MG PER 5 ML USP (NSAID)

**Dye Free**

**Original  
Berry Flavor**

**SEE NEW WARNINGS**

**LASTS UP TO 8 HOURS**

**8**

4 FL OZ (118 mL)

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

**Drug Facts**

Active Ingredient	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

## CHILDRENS IBUPROFEN ORAL SUSPENSION

ibuprofen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69618-078
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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**IBUPROFEN** (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM) | **IBUPROFEN** | 100 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	

### Product Characteristics

<b>Color</b>	brown (white to light brown)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY (Dye Free)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69618-078-54	1 in 1 CARTON	12/02/2024	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**NO COATING**

Children's Ibuprofen Oral Suspension (NSAID)  
100 mg per 5 mL  
For Ages 2 to 11 years

NDC 69618-078-54



**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:  

- stools that are black or dark red
- stools that are bloody or black
- has bloody or black stool
- has stomach pain that does not get better
- child has symptoms of heart problems or stroke:  
  - chest pain
  - trouble breathing
  - swelling in one part or side of body
  - slurred speech
  - lag in walking
- 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**

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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**  
Acacia, croscarmellose sodium, hydroxypropyl methylcellulose, polyethylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

**Questions or comments?**  
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Distributed by:  
Reliable-1 Labs LLC  
88 W Hawthorne Ave Suite #10  
Valley Stream, NY 11580

BX-18Z



**PAIN RELIEVER / FEVER REDUCER**  
Compare to the active ingredient in Children's Motrin®\*\*

**Children's Ibuprofen Oral Suspension**  
100 MG PER 5 ML USP (NSAID)

**Dye Free**

**Original Berry Flavor**

**SEE NEW WARNINGS** Ages 2-11

**LASTS UP TO 8 HOURS**

4 FL OZ (118 ML)

**Important: Read all product information before using. Keep this list 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	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
- swelling
- skin redness

If an allergic reaction occurs, stop use and seek medical help right away.

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Do not use:  

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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/02/2024	

**Labeler** - Reliable 1 Laboratories LLC (079718111)

Revised: 1/2025

Reliable 1 Laboratories LLC