

## **CHILDRENS IBUPROFEN- ibuprofen suspension**

**Precision Dose Inc.**

**Reference Label Set Id: 1984374e-7639-4a4f-bf96-a614e663e0c4**

-----

### **CHILDREN'S IBUPROFEN ORAL SUSPENSION**

Berry Flavor

100 mg/5 mL 200 mg/10 mL

***For Hospital Use Only***

#### ***Drug Facts***

#### **Active ingredient (in each 5 mL)**

Ibuprofen 100 mg (NSAID)<sup>1</sup>

---

1 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

### **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**

- give 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

- **Use as directed per healthcare professional.**
- **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.
- if needed, repeat dose every **6-8 hours**
- do not use more than **4 times a day**

### Dosing Chart

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
under 24 lbs	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 at 20-25°C (68-77°F)
- do not freeze

### 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

**Alcohol Free, Gluten Free**

## Questions or comments?

1-800-397-9228

## How Supplied

NDC 68094-037-58

5 mL per unit dose ENFit syringe  
Fifty (50) syringes per shipper

NDC 68094-494-58

5 mL per unit dose syringe  
Fifty (50) syringes per shipper

NDC 68094-494-61

5 mL per unit dose cup  
One hundred (100) cups per shipper

NDC 68094-494-62

5 mL per unit dose cup  
Thirty (30) cups per shipper

NDC 68094-503-61

10 mL per unit dose cup  
One hundred (100) cups per shipper

NDC 68094-503-62

10 mL per unit dose cup  
Thirty (30) cups per shipper

Packaged By

**Precision Dose, Inc.**

South Beloit, IL 61080

For inquiries call Precision Dose, Inc. at 1-800-397-9228 or email  
[druginfo@precisiondose.com](mailto:druginfo@precisiondose.com)

LI587 Rev. 06/23

## PRINCIPAL DISPLAY PANEL - 5 mL Cup Label

NDC 68094-494-59

PrecisionDose™

Children's IBUPROFEN

Oral Suspension 100 mg/5 mL

Pkg: Precision Dose, Inc. S. Beloit, IL 61080

Delivers 5 mL  
Hospital  
Use Only  
694 R2  
6498

NDC 68094-494-59  
PrecisionDose™

Children's IBUPROFEN  
Oral Suspension 100 mg/5 mL  
Pkg: Precision Dose, Inc., S. Beloit, IL 61080



Each 5 mL contains: sodium 2 mg  
Store at 20-25°C  
(68-77°F)  
Alcohol Free  
Gluten Free  
(NSAID)  
Shake Well



**Children's Ibuprofen Oral Suspension**

Berry Flavor  
100 mg/5 mL 200 mg/10 mL

**For Hospital Use Only**

LI1651 Rev. 10/24

**Drug Facts**

**Active ingredient**

(in each 5 mL)

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

**Purposes**

**When using this product**

- give 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**

- Use as directed per healthcare professional.
- 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.

- 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

- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day

#### Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)**
under 24 lbs	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 at 20-25°C (68-77°F)
- do not freeze

### 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

### Alcohol Free, Gluten Free

**Questions or comments?** 1-800-397-9228

### How Supplied

NDC 68094-037-58

5 mL per unit dose ENFit syringe  
Fifty (50) syringes per shipper

NDC 68094-494-58

5 mL per unit dose syringe  
Fifty (50) syringes per shipper

NDC 68094-494-61

5 mL per unit dose cup  
One hundred (100) cups per shipper

NDC 68094-494-62

5 mL per unit dose cup  
Thirty (30) cups per shipper

NDC 68094-503-61

10 mL per unit dose cup  
One hundred (100) cups per shipper

NDC 68094-503-62

10 mL per unit dose cup  
Thirty (30) cups per shipper

#### Packaged By

Precision Dose, Inc.  
South Beloit, IL 61080

For inquiries call Precision Dose, Inc. at 1-800-397-9228  
or email [druginfo@precisiondose.com](mailto:druginfo@precisiondose.com)

LI1651 Rev. 10/24

## PRINCIPAL DISPLAY PANEL - 5 mL Syringe Label

NDC# 68094-494-58

Children's IBUPROFEN Oral Suspension, 100 mg/5 mL

Delivers 5 mL (NSAID) For Hospital Use Only

Each 5 mL contains: sodium 2 mg

Alcohol Free

Gluten Free

Store at 20°-25°C (68°-77°F) Protect from freezing

Pkg: Precision Dose, Inc. S. Beloit, IL 61080

LSY495 Rev. 04/11

For Oral Use Only



**Children's Ibuprofen Oral Suspension**

Berry Flavor  
 100 mg/5 mL 200 mg/10 mL  
**For Hospital Use Only**  
 LI1651 Rev. 10/24

**Drug Facts**

**Active ingredient** **Purposes**  
 (in each 5 mL)  
 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

**When using this product**

- give 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**

- Use as directed per healthcare professional.
- 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.
- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)**
under 24 lbs	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 at 20-25°C (68-77°F)
- do not freeze

**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



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

**Alcohol Free, Gluten Free**

**Questions or comments?** 1-800-397-9228

**How Supplied**

NDC 68094-037-58  
5 mL per unit dose ENFit syringe  
Fifty (50) syringes per shipper

NDC 68094-494-58  
5 mL per unit dose syringe  
Fifty (50) syringes per shipper

NDC 68094-494-61  
5 mL per unit dose cup  
One hundred (100) cups per shipper

NDC 68094-494-62  
5 mL per unit dose cup  
Thirty (30) cups per shipper

NDC 68094-503-61  
10 mL per unit dose cup  
One hundred (100) cups per shipper

NDC 68094-503-62  
10 mL per unit dose cup  
Thirty (30) cups per shipper

Packaged By  
Precision Dose, Inc.  
South Beloit, IL 61080

For inquiries call Precision Dose, Inc. at 1-800-397-9228  
or email [druginfo@precisiondose.com](mailto:druginfo@precisiondose.com)

LI1651 Rev. 10/24

## CHILDRENS IBUPROFEN

ibuprofen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68094-494(NDC:0113-0897)
<b>Route of Administration</b>	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)	
D&C yellow NO. 10 (UNII: 35SW5USQ3G)	

<b>FD&amp;C red NO. 40</b> (UNII: WZB9127XOA)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>high fructose corn syrup</b> (UNII: XY6UN3QB6S)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68094-494-62	3 in 1 CASE	04/13/2004	
1		10 in 1 TRAY		
1	NDC:68094-494-59	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:68094-494-61	10 in 1 CASE	04/13/2004	
2		10 in 1 TRAY		
2	NDC:68094-494-59	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:68094-494-58	5 in 1 CASE	04/13/2004	01/31/2025
3		10 in 1 BAG		
3		5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074937	04/13/2004	

**Labeler** - Precision Dose Inc. (035886746)