CHILDRENS IBUPROFEN- ibuprofen suspension
Precision Dose Inc.

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)[1]

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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
- **Important: Read all product information before using.**
- **This product is intended for use in children.**

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 cups 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
- See individual label or shipper for lot number and expiration date.

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

How Supplied

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

Distributed By
Perrigo Company
Allegan, MI 49010

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

LI587 Rev. 02/18

PRINCIPAL DISPLAY PANEL - 5 mL Cup 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

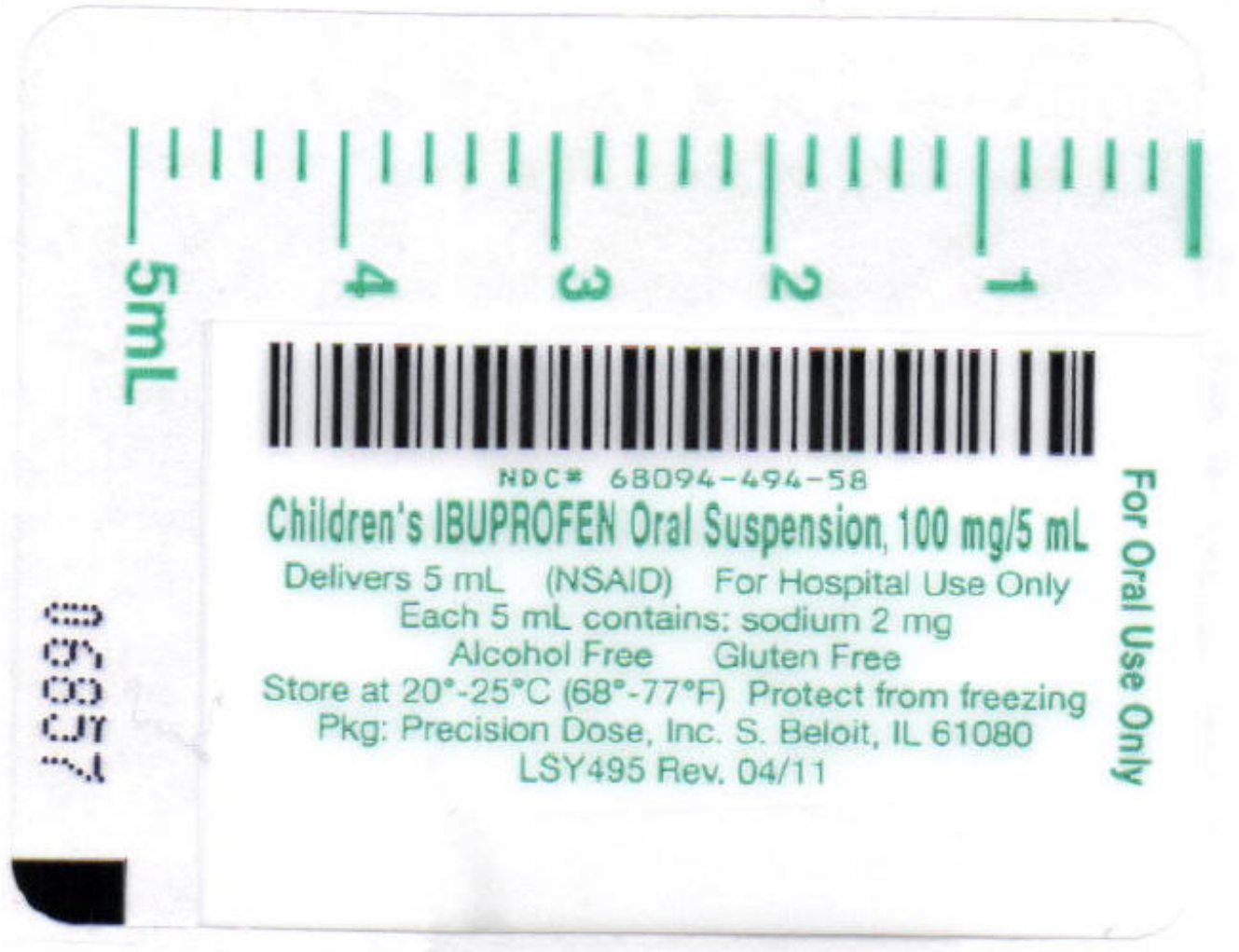
Alcohol Free
Gluten Free

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



PRINCIPAL DISPLAY PANEL - 200 mg/10 mL Lid

NDC 68094-503-59

PrecisionDose™

Children's IBUPROFEN
Oral Suspension
200 mg/10 mL

Delivers 10 mL Shake Well (NSAID) Alcohol Free Gluten Free
Each 5 mL contains: sodium 2 mg

Hospital Use Only
Store at 20-25°C (68-77°F)
Pkg. By: Precision Dose, Inc.
S. Beloit, IL 61080

CHILDRENS IBUPROFEN

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68094-494
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)	
D&C yellow NO. 10 (UNII: 35SW5USQ3G)	
FD&C red NO. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
high fructose corn syrup (UNII: XY6UN3QB6S)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics			
Color	ORANGE	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

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	
3		10 in 1 BAG		
3		5 mL in 1 SYRINGE; Type 0: Not a Combination Product		

Marketing Information

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

CHILDRENS IBUPROFEN

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68094-503
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Ibuprofen (UNII: WK2XYI10QM) (Ibuprofen - UNII:WK2XYI10QM)	Ibuprofen	200 mg in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
anhydrous citric acid (UNII: XF417D3PSL)	
D&C yellow NO. 10 (UNII: 35SW5USQ3G)	

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

Product Characteristics

Color	ORANGE	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68094-503-62	3 in 1 CASE	09/14/2006	
1		10 in 1 TRAY		
1	NDC:68094-503-59	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:68094-503-61	10 in 1 CASE	09/14/2006	
2		10 in 1 TRAY		
2	NDC:68094-503-59	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074937	09/14/2006	

Labeler - Precision Dose Inc. (035886746)

Establishment

Name	Address	ID/FEI	Business Operations
L. Perrigo Company		006013346	MANUFACTURE(68094-494, 68094-503)

Revised: 10/2018 Precision Dose Inc.