

**IBUPROFEN- ibuprofen suspension**  
**Strides Pharma Inc**

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**Children's Ibuprofen Oral Suspension, USP**  
**Drug Facts**

**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**

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
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 if carton tape or bottle wrap imprinted "SEALED FOR YOUR PROTECTION" is broken or missing**

**Inactive ingredients**

Acesulfame potassium, anhydrous citric acid, D&C yellow no. 10, FD&C red no. 40, glycerin, hypromellose, mix berry flavor, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

**Questions or comments ?**

Call **1-877-244-9825**

Manufactured by:

**Strides Pharma Science Ltd.**

Bengaluru - 562106, India.

Distributed by:

**Strides Pharma Inc.,**

East Brunswick, NJ 08816

Revised: 10/2020

**PRINCIPAL DISPLAY PANEL**

***See New Warnings***

NDC 59556-876-72

***For Ages 2 to 11 Years***

***Children's Ibuprofen Oral Suspension, USP (NSAID)***

***100 mg per 5 mL***

***Pain Reliever / Fever Reducer***

***Lasts up to***

***8 hours***

***Alcohol Free***

***Berry Flavor***

***4 fl oz (120 mL)***



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Strides Pharma Inc.

100 mg per 5 mL

Oral Suspension, USP

Ibuprofen

Children's

For Ages 2 to 11 Years

NDC 59556-876-72

See New Warnings

1038006

GRAIN DIRECTION

Drug Facts (continued)

Dozing 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
72-85 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)
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Questions or comments?

Call 1-877-244-9825

Code No.: KR\DRUGS\XXX\XX\XXX\XX

Manufactured by: Strides Pharma Science Ltd. Bengaluru - 562106, India.

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Revised: 10/2020



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See New Warnings

NDC 59556-876-72

For Ages 2 to 11 Years

Children's

Ibuprofen

Oral Suspension, USP

100 mg per 5 mL

Pain Reliever/Fever Reducer (NSAID)

Lasts up to 8 hours Alcohol Free



Berry Flavor 4 fl oz (120 mL)

Strides Pharma Inc.

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 (in each 5 mL) Ibuprofen 100 mg (NSAID)\* Pain reliever/fever reducer

\*nonsteroidal anti-inflammatory drug

Uses temporarily:

- relieve 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
- take a blood thinning (anticoagulant) or steroidal drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take 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

Drug Facts (continued)

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:
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- child has symptoms of heart problems or stroke:
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- the child does not get any relief within first day (24 hours) of treatment
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Directions

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- mL = milliliter
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- 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

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

**Active ingredient (in each 5 mL):** *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.

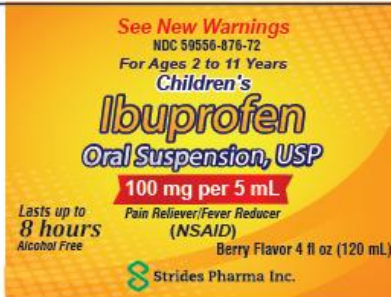
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**Do not use** ■ if the child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer ■ right before or after heart surgery.

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**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 over dose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Directions** ■ this product does not contain directions for 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 ▶

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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 carton is opened or if carton tape or bottle wrap imprinted "SEALED FOR YOUR PROTECTION" is broken or missing

**Inactive ingredients** acesulfame potassium, anhydrous citric acid, D&C yellow no. 10, FD&C red no. 40, glycerin, hypromellose, mix berry flavor, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

**Questions or comments?** Call 1-877-244-9825

Code No.: KR/DRUGS/XXX/XX/XXX/XX

Manufactured by: **Strides Pharma Science Ltd.** Distributed by: **Strides Pharma Inc.** Revised: 10/2020  
 Bengaluru - 562106, India. East Brunswick, NJ 08816

LOT:

EXP:



1086005

# IBUPROFEN

ibuprofen suspension

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59556-876
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	100 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35S5W5USQ3G)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>WATER</b> (UNII: 059QF0K00R)	

## Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	
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<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:59556-876-72	1 in 1 CARTON	02/21/2022	
1		120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211666	02/21/2022	

**Labeler** - Strides Pharma Inc (078868278)

### Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	ANALYSIS(59556-876) , MANUFACTURE(59556-876) , PACK(59556-876)

Revised: 3/2021

Strides Pharma Inc