

IBUPROFEN - ibuprofen suspension
Strides Pharma Inc

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

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 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: 04/2022

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)



4983

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)
- 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, polyacorbate 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. Bengaluru - 562106, India.

Distributed by: Strides Pharma Inc., East Brunswick, NJ 08816

Revised: 10/2020



N 3 1595561876721

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 steroid 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:
 - 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 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

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.

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. ▶

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)
Berry Flavor 4 fl oz (120 mL)
Strides Pharma Inc.

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 ▶

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 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:

NO VARNISH ZONE

1036005

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

See New Warnings

NDC 59556-234-72

For Ages 2 to 11 Years

Children's Ibuprofen Oral Suspension

100 mg per 5 mL

Pain Reliever / Fever Reducer

(NSAID)

Lasts up to

8 hours

Alcohol Free

Grape Flavor

4 fl oz (120 mL)

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.

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. ▶

See New Warnings

NDC 59655-234-72

For Ages 2 to 11 Years

Children's Ibuprofen Oral Suspension

100 mg per 5 mL

Pain Reliever/Fever Reducer

Lasts up to
8 hours
Alcohol Free

Strides Pharma Inc.

Grape Flavor
4 fl oz (120 mL)

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 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

*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, glycerin, grape flavor, hypromellose, opatint concentrated color dispersion G 500000 purple, 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.
Bengaluru - 562106, India.

Distributed by:
Strides Pharma Inc.,
East Brunswick, NJ 08816

Revised: 04/2022

LOT:

EXP:

NO VARNISH ZONE



1000000



100 mg per 5 mL

Oral Suspension

Children's

Ibuprofen

For Ages 2 to 11 Years

NDC 59556-234-72

See New Warnings



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Drug Facts (continued)

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL
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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, glycerin, grape flavor, hydroxypropyl methylcellulose, opalint concentrated color dispersion G 300000 purple, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

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

See New Warnings

NDC 59556-234-72

For Ages 2 to 11 Years

Children's

Ibuprofen

Oral Suspension

100 mg per 5 mL

Pain Reliever/Fever Reducer

(NSAID)

Lasts up to
8 hours

Alcohol Free

Grape 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
(in each 5 mL)
Ibuprofen 100 mg (NSAID)*

Purpose
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
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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
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- 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

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- 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
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 - leg swelling
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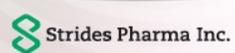
NO VARNISH ZONE

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

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

Distributed by:
Strides Pharma Inc.,
East Brunswick, NJ 08816

Revised: 04/2022



NO VARNISH ZONE

LOT } To be
EXP } over pr



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

See New Warnings

NDC 59556-235-72

For Ages 2 to 11 Years
Children's Ibuprofen Oral Suspension
100 mg per 5 mL
Pain Reliever / Fever Reducer
Lasts up to
8 hours
Alcohol Free
Bubblegum flavor
4 fl oz (120 mL)

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
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Uses temporarily: ■ relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache ■ reduces fever

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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.

See New Warnings
 NDC 69555-235-72
 For Ages 2 to 11 Years

**Children's
 Ibuprofen
 Oral Suspension**

100 mg per 5 mL

Pain Reliever/Fever Reducer
 Strides Pharma Inc. Bubblegum Flavor
 4 fl oz (120 mL)

Lasts up to
8 hours
 Alcohol Free

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.

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Dosing Chart

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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, bubblegum flavor, D&C yellow no. 10, FD&C red no. 40, glycerin, hypromellose, 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.
 Bengaluru - 562106, India.

Distributed by:
 Strides Pharma Inc.,
 East Brunswick, NJ 08816

Revised: 04/2022

LOT:

EXP:

NO VARNISH ZONE



1X0000X



4983

100 mg per 5 mL

Ibuprofen
Children's
Oral Suspension

For Ages 2 to 11 Years

NDC 59556-235-72
See New Warnings



10X000X

Drug Facts (continued)

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

Inactive ingredients

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

Questions or comments?

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3 159556123572 6

See New Warnings

NDC 59556-235-72

For Ages 2 to 11 Years

Children's
Ibuprofen
Oral Suspension

100 mg per 5 mL

Pain Reliever/Fever Reducer
(NSAID)

Lasts up to
8 hours
Alcohol Free

Bubblegum 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 (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.

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

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:
 - 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

NO VARNISH ZONE

LOT } To be
EXP } over

NO VARNISH ZONE



59556

IBUPROFEN
ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59556-876
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KOOR)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TRIACETIN (UNII: XHX3C3X673)	

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:59556-876-72	1 in 1 CARTON	03/24/2025	
1		120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59556-876-01	1 in 1 CARTON	03/24/2025	
2		240 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	03/24/2025
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IBUPROFEN

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59556-234
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-234-72	1 in 1 CARTON	03/24/2025	
1		120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59556-234-01	1 in 1 CARTON	03/24/2025	
2		240 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	03/24/2025	

IBUPROFEN

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59556-235
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
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-235-01	1 in 1 CARTON	03/24/2025	
1		240 mL in 1 CARTON; Type 0: Not a Combination Product		
2	NDC:59556-235-72	1 in 1 CARTON	03/24/2025	
2		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	03/24/2025	

Labeler - Strides Pharma Inc (078868278)

Registrant - Strides Pharma Global Pte. Ltd. (659220961)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	ANALYSIS(59556-876, 59556-234, 59556-235) , MANUFACTURE(59556-876, 59556-234, 59556-235) , PACK(59556-876, 59556-234, 59556-235)

Revised: 3/2025

Strides Pharma Inc