

CHILDRENS IBUPROFEN ORAL SUSPENSION- ibuprofen suspension
AptaPharma Inc.

Children's Ibuprofen Oral Suspension

Drug Facts

Active ingredient
(in each 5 mL)

Ibuprofen 100 mg*

*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 printed bottle neckband is broken or missing**
- see bottom panel for lot number and expiration date

Inactive ingredients

Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

Questions or comments?

Call weekdays from 9:30 AM to 4:30 PM EST at
1-877-798-5944

Package Labeling

New Warnings NDC 76281-119-24

**Compare To The
Active Ingredient In
Children's Motrin [®]****

Children's

Ibuprofen

Oral Suspension (NSAID)

100 mg per 5 mL

Pain Reliever/Fever Reducer

LASTS UP TO 8 HOURS

Alcohol Free

Original

Berry Flavor

4 FL OZ (118mL)

Important Read all product information before using.

Keep this box for important information.

This product is intended for use in children.

****This product is not manufactured or distributed by McNeil**

Consumer Healthcare, distributor of Children's Motrin[®].

Manufactured by:

APTAPHARMA Inc.

1533 Union Avenue

Pennsauken, NJ 08110, USA

BX-065

For Ages 2 to 11 Years

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

See New Warnings NDC 76281-119-24

Compare To The
Active Ingredient In
Children's Motrin[®]**

For Ages 2 to 11 Years

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer

LASTS UP TO 8 HOURS

Alcohol Free



Original
Berry Flavor

4 FL OZ (118 mL)



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

Acetosulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polyorbate S0, polyethylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

Questions or comments?

Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-798-5944

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

 Manufactured by:
APTAPHARMA, Inc.
1533 Union Avenue
Perth Amboy, NJ 08810, USA BX-085

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)..... Pain reliever/
nonsteroidal anti-inflammatory drug

Purpose

Uses temporarily:

- relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache
- soothes 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
- dizziness

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

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
- arm aches
- 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. (1-800-222-1232)

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

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

Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen 100 mg (NSAID)*..... Pain reliever/fever reducer

Purpose

*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

AP
Aptapharma

NDC 76281-119-24

**Children's
Ibuprofen**

Oral Suspension (NSAID)
100 mg per 5 mL

4 fl oz
(118 mL)

Pain Reliever/Fever Reducer

Original Berry Flavor

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



Drug Facts (continued)

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 below. 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 printed neckband is broken or missing

Inactive ingredients Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystal line cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose and xanthan gum

Questions or comments?
Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-798-5944.

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

Manufactured by:
APTAPHARMA Inc. 1533 Union Avenue
Pennsauken, NJ 08110, USA

res

CHILDRENS IBUPROFEN ORAL SUSPENSION

ibuprofen suspension

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76281-119 |
| 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) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KOOR) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SUCROSE (UNII: C151H8M554) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|-----------------|------------------|---------------------|--|
| Color | orange | Score | |
| Shape | | Size | |
| Flavor | BERRY (Original) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76281-119-24 | 1 in 1 CARTON | 09/30/2020 | |
| 1 | | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA210602 | 09/30/2020 | |

Labeler - AptaPharma Inc. (790523323)

Registrant - AptaPharma Inc. (790523323)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

Revised: 12/2025

AptaPharma Inc.