

**CHILDRENS IBUPROFEN GRAPE- ibuprofen suspension**  
**AptaPharma Inc.**

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**Children's Ibuprofen Oral Suspension (NSAID) - Grape Flavor**

**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 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 Red #33, FD&C Blue #1, 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: Children's Ibuprofen Oral Suspension Original Berry Flavor**

**See New Warnings**

**NDC 76281-126-24**

**AP Safe**

**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**

**Grape Flavor**

**4 FL OZ (118 mL)**

**Important: Read all product information before using. Keep the 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**

**Carton Label**

For Ages 2 to 11 Years

# Children's Ibuprofen

Oral Suspension (NSAID)  
100 mg per 5 mL

See New Warnings

NDC 76281-126-24



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



Dosage Cup Included

Grape Flavor

4 FL. OZ (118 mL)



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### Drug Facts (continued)

- 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

### 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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| 60-71 lbs   | 9-10 years    | 12.5 mL      |
| 72-95 lbs   | 11 years      | 15 mL        |

\*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

Acetylsalicylic acid, anhydrous citric acid, carbonylmethylcellulose sodium, D & G Red #33, FD&C Blue #1, flavors, glycerin, microcrystalline cellulose, polyorbate 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 1-732-314-4550

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

Manufactured by:  
AptaPharma Inc.,  
1533 Union Ave.,  
Pennsauken, NJ 08110

AP-BX-16

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/  
Nonsteroidal anti-inflammatory drug  
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 redness
- itch
- hiccups

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

## Bottle Label

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



NDC 76281-126-24

**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 ■ 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

**Purpose**

Children's  
**Ibuprofen**

Oral Suspension (NSAID)

100 mg per 5 mL

4 FL OZ

Pain Reliever/Fever Reducer (118 mL)

Grape Flavor

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.

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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 **Stop use and ask a doctor if** ■ child experiences any of the following signs of stomach bleeding: • feels faint



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AP-LR-31

Lot/ Exp Date

PEEL HERE

Hinge

**Drug Facts (continued)**

• 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 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

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| 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 Red #33, FD&C Blue #1, 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 1-732-314-4550

Manufactured by: AptaPharma Inc., 1533 Union Ave. Pennsauken, NJ 08110

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**CHILDRENS IBUPROFEN GRAPE**

ibuprofen suspension

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:76281-126

**Route of Administration**

ORAL

**Active Ingredient/Active Moiety**

| Ingredient Name  |  | Basis of Strength                                     | Strength             |                    |
|--|--|---|----------------------|--------------------|
| IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM) |  | IBUPROFEN   | 100 mg in 5 mL       |                    |
| <b>Inactive Ingredients</b>                                |  |   |                      |                    |
| Ingredient Name  |  | Strength  |                      |                    |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)                    |  |   |                      |                    |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)                   |  |   |                      |                    |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)           |  |   |                      |                    |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L)                          |  |   |                      |                    |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                         |  |   |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)                                |  |   |                      |                    |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)              |  |   |                      |                    |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)                          |  |   |                      |                    |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                        |  |   |                      |                    |
| WATER (UNII: 059QF0KO0R)                                   |  |   |                      |                    |
| SODIUM BENZOATE (UNII: OJ245FE5EU)                         |  |   |                      |                    |
| SUCROSE (UNII: C151H8M554)                                 |  |   |                      |                    |
| XANTHAN GUM (UNII: TTV12P4NEE)                             |  |   |                      |                    |
| <b>Product Characteristics</b>                             |  |   |                      |                    |
| Color  | purple                                   | Score   |                      |                    |
| Shape  |  | Size  |                      |                    |
| Flavor   | GRAPE                                    | Imprint Code  |                      |                    |
| Contains   |  |   |                      |                    |
| <b>Packaging</b>   |  |   |                      |                    |
| #  | Item Code                                | Package Description                                   | Marketing Start Date | Marketing End Date |
| 1  | NDC:76281-126-24                         | 1 in 1 CARTON   | 01/31/2024           |                    |
| 1  |  | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| <b>Marketing Information</b>                               |  |   |                      |                    |
| 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    |
|-----------------|---------|-----------|------------------------|
| AptaPharma Inc. |         | 790523323 | manufacture(76281-126) |

Revised: 2/2024

AptaPharma Inc.