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 lever, 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 heartbum
■ 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 lor any serious condition
■ taking any other drug

When using this product
■ take with food or milk if stomach upset occurs

Slop 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 20-2S° C (68-77° F)
- **do not use if carton is opened or printad bottle neckband is broken or missing**
- see bottom panel for lot number and expiration date

Inactive ingredients
Acesullame 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 (118 mL)

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

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

Consumer Healthcare, distributor of Children's Motrin®.

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

BX-065

Drug Facts (continued)

Other information

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AptaPharma

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

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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

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
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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: 059QF0KO0R)	
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

AptaPharma Inc.		790523323	manufacture(76281-119)

Revised: 12/2024 AptaPharma Inc.