# CHILDRENS IBUPROFEN ORAL SUSPENSION, BUBBLE GUMibuprofen suspension Best Choice

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# Children's Ibuprofen Oral Suspension, Bubble Gum 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

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

<sup>\*</sup>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 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

1-732-314-4550

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Package Labeling: Best Choice® Children's Ibuprofen Oral Suspension, Bubble Gum Flavor

Best Choice®

Children's

**Ibuprofen** 

Oral Suspension (NSAID)

100 mg per 5 ml

Pain Reliever/Fever Reducer

COMPARE TO THE

ACTIVE INGREDIENT
IN CHILDREN'S

MOTRIN®\*\*

**LASTS UP TO** 

8 HOURS

For ages

2 to 11 years

**Bubble Gum Flavor** 

4 FL OZ (118 mL)

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®

PROUDLY DISTRIBUTED BY:

**VALUE MERCHANDISERS, CO.** 

**5000 KANSAS AVE** 

KANSAS CITY, KS 66106

Carton



### Drug Facts (continued)

- child has asthma
   child is taking a diuretic

Ask a doctor or pharmacist before use if the
under a doctor's care for any serious condit
taking any other drug

- When using this product

  take with food or milk if stomach upset occurs

- 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:

   venits blood

   least blood; or black stoods

   has stomach pain that does not get better

   child has symptoms of heart problems or stroke:

   child has symptoms of heart problems or stroke:

   chest pain

   weakness in one part or side of body

   slarred sphech

   lag swelling

   the child does not get any relief within first day

  (24 hours) of treatment

- (24 hours) of treatment
  fiver or pain gets werse or lasts more than 3 days
  redness or swelling is present in the painful area
  any new symptoms appear

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   use only enclosed dosing cup. Do not use any other design adm.
- use only unarranu variety 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

  | Comment | Comme

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Drug Facts (continued)

- Other information

  \*\*each 5 mL centains sodium 2 mg

  \*\*store between 20-25°C (B8-779)

  \*\*do not use if carton is opened or printed bottle

  \*\*neckband is broken or missing

  \*\*see bottlem panel for lot rumber and expiration date

Inactive ingredients
Aceutteme potasskim, antydrus citira act, actorymetrylecilideae sodium, D&C Red et 33, FO&C Red 440, Stavys, glycarin, micropsystalline cellulase, polysorbal 80, peoplylen glycol, purified water, sodium berzoala, sucrose, and xamber gum

Questions or comments? Call weekdays from 9:30 AM to 4:30 PM EST at 1-732-314-4550

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Scan here for more product information. Call 1-844-292-1112 for more product information.





BX-147



## Drug Facts

Active ingredient

(in each 5 mL) ouprofen 100 mg (NSAID)". "nonsteroidal anti-inflammatory drug fever reducer

Purpose

Translanded arti-Hammatary drug lever reducer

USGS temporarily:

In diserves minor oches and paire due to the common cold,

ful sone threat, headache and toothache

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"warnings

Allergy alert: libuproten may cause a severa allergic
reactor, especially in people allergic to aspisin. Symptoms

may include:

In these In facial swelling In ashma (wheezing)

In shock In skin moderning In ashma (wheezing)

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In shock In skin moderning

In allergic reaction cocus, stop use and seek medical

help right away.

Stomach bleeding warning: This productiontains an

NSAID, which may cause severe stomach bleeding. The

chance is higher if your child:

In last had stomach ulcers or bleeding proterns

I takes a blood thrinning lenticoapplaint or steroid drug

It takes other drugs containing prescription or

noonrescription NSAIDs (aspini, buptofie),

naproven, or others)

I takes more of for a lenger time than directed

Heart attack and stroke warning: NSAIDs, except

asprin, increase the risk of heart attack, heart failure, and

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■ takes more or for a longer time than dincored Heart attack and stroke warning: NSAID, except aspirin, increase the risk of heart attack, heart failure, and stude. These can be statal. The risk is higher if you use more than directed or for longer than directed. Sore throat warning: Severe or persistent sore throat or sere throat excompanied by high fever, headache, rausea, and verniting may be serious. Consult doctor promptly, but 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 ibuprofer
  or any other pain relieves/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

- Child less a naxivy or somation processing, social as hearthcars
   child has problems or serious side effects from taking pain refleves or flevet reduces.
   child has soot been dispirition flatics
   child has soot a lot of haif due to homiting or clearhea
   child has shigh body pressure, heart dispirition for child has high body operation, heart dispirition for child has high body operation.

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### **Bottle**

Drug Facts Active ingredient (In each 5 mL)

Purpose

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

nonsteroidal anti-inflammatory drug USBS temporarily:

relieves minor aches and pains due to the common cold, flu, sore throat, headache and

common colo, ill., sole throat, heasache and toothache # reduces fever Warnings
Allergy alert: Buprofen may cause a severa allergic reaction, especially in people allergic to appirin. Symptoms may include: # hives # stoial yealting # setting hippering # severa electric # setting hippering # severa electric # setting hippering # setting hipperin swelling = asthma (wheezing) = shock = skin reddening = rash = bilsters. If an allergic reaction recoming Fiscal Classification and allerge 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 preccription or nonprescription NS/NDs (aspirin, buprofen, naproxen, or others) # takes more or for a longer time than directed. Heart attack and stroke warning: NSADs, 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 warnings 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

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heartbum # child has problems or serious side effects from taking pain relivers or lever 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 stoke # child has actima # child is laiding a fluretic 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 flood or milk if stomach updet doctors Stop use and ask a doctor if # child experiences any of the floillowing signs of stomach bleeding: • feels faint • vomits blood • has bloody or black shoots • has stomach pain that does not better # child has symptoms of heart problems 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 relet within first day (24 hours) of treatment
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present in the painful area ■ any new symptoms appear
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Directions . this product does not contain directions or complete

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dose, otherwise use age, # use only enclosed dosing out. 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\*\*

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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 printed neckband is broken or missing

Inactive ingredients Acesultame potassium, anhydrous chric acid, carbonmethylcellulose sodium, D&C Red # 33, FD&C Red # 40, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoale, sucrose, and xanthan gum

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# CHILDRENS IBUPROFEN ORAL SUSPENSION, BUBBLE GUM

ibuprofen suspension

### **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:63941-127 **Route of Administration ORAL**

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SUCROSE (UNII: C151H8M554)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	pink	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

P	Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:63941-127- 24	1 in 1 CARTON	01/01/2025		
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA210602	01/01/2025	

# Labeler - Best Choice (868703513)

# Registrant - AptaPharma Inc. (790523323)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>

AptaPharma Inc.	790523323	manufacture(63941-127)
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Revised: 1/2025 Best Choice