

IBUPROFEN PAIN RELIEVER/ FEVER REDUCER- ibuprofen suspension
Amneal Pharmaceuticals

Ibuprofen Oral Suspension, USP (NSAID)
Pain Reliever/ Fever Reducer
100 mg/ 5 mL

OTC - ACTIVE INGREDIENT

Active Ingredient

(in each 5 mL = 1 teaspoon)

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

OTC - PURPOSE

Purpose

Pain reliever/ fever reducer

INDICATIONS AND USAGE

Uses

Temporarily:

- Relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache
- Reduces fever

WARNINGS

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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chances are higher if your child:

- has had stomach ulcers or bleeding problems
- takes a blood thinning (anticoagulant) or steroid drug
- takes other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others)
- takes more or for a longer time 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.

OTC - DO NOT USE

Do not use:

- if the child has ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

OTC - ASK DOCTOR

Ask a doctor before use if:

- child has problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to your child
- child has a history of stomach problems, such as heartburn
- 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, or kidney disease
- child has asthma
- child is taking a diuretic

OTC - ASK DOCTOR/PHARMACIST

Ask a doctor or pharmacist before use if the child is:

- under doctor's care for any serious condition
- taking any other drug

OTC - WHEN USING

When using this product:

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

OTC - STOP USE

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
- the child does not get any relief within the 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

OTC - KEEP OUT OF REACH OF CHILDREN

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)

DOSAGE AND ADMINISTRATION

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- shake well before using
- find right dose on chart below (if possible, use weight to dose; otherwise use age)
- use only enclosed measuring cup
- 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 (tsp or mL)
	under 2 years	ask a doctor
24-35 lbs	2-3 years	1 tsp or 5 mL
36-47 lbs	4-5 years	1 ½ tsp or 7.5 mL
48-59 lbs	6-8 years	2 tsp or 10 mL
60-71 lbs	9-10 years	2 ½ tsp or 12.5 mL
72-95 lbs	11 years	3 tsp or 15 mL

OTHER INFORMATION

Other information

- each teaspoon contains: **sodium 2 mg**
- store between 20° to 25°C (68° to 77°F)
- do not use if bottle wrap, or imprinted foil inner seal is broken or missing
- see bottom panel for lot number and expiration date

INACTIVE INGREDIENTS

acesulfame-potassium, anhydrous citric acid, D&C yellow # 10, FD&C red # 40, glycerin, NA bubble gum flavor FQ5511, polysorbate 80 (tween 80), purified water, sodium benzoate, sucrose, xanthan gum

OTC - QUESTIONS

Questions or Comments? Call 1-877-835-5472,
Monday through Friday 9AM - 5PM EST.

Keep the carton.

It contains important information.

See end panel for expiration date.

*This product is not manufactured or distributed by McNeil-PPC, Inc., distributor of Children's Motrin®.

Distributed by: **Amneal Pharmaceuticals**

Glasgow, KY 42141

Rev. 07-2011

PACKAGE LABEL, PRINCIPAL DISPLAY PANEL

*Compare to Children's **Motrin**® active ingredient
SEE NEW WARNINGS INFORMATION
NDC 65162-672-86
For Ages 2 to 11

Ibuprofen

Oral Suspension, USP

100 mg/5 mL (teaspoon)
Pain Reliever/Fever Reducer (NSAID)*
Lasts up to 8 hours
Bubble Gum Flavor
4 FL OZ (118mL)



Do not use if imprinted foil inner seal is broken or missing.

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

Active ingredient (in each 5 mL = 1 teaspoon) 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 redness, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains a non-steroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if your child:
has had stomach ulcers or bleeding problems
takes a blood thinner (anticoagulant) or steroid drug
takes other drugs containing prescription or non-prescription NSAIDs, aspirin, ibuprofen, naproxen, or others
takes more or for a longer time than directed
Stomach 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 any other pain reliever/fever reducer, right before or after heart surgery. **Ask a doctor before use if:** child has problems or serious side effects from taking pain relievers or fever reducers
stomach bleeding warning applies to your child
child has a history of stomach problems, such as heartburn
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 or kidney disease
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

Distributed by: **Amneal Pharmaceuticals**, Glasgow, KY 42141
Rev. 07, 2011

*This product is not manufactured or distributed by MOWH-PPC, Inc., distributor of Children's Motrin®.

Lot No: _____
Exp. Date: _____

3 65162-672-86 2

PEEL BACK FOR ADDITIONAL DRUG FACTS

When using this product take with food or milk if stomach upset occurs the risk of heart attack or stroke may increase if you use more than directed or for longer than directed. **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. the child does not get any relief within the 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. find right dose on chart below. if possible, use weight to dose; otherwise use age. use only enclosed measuring cup. 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 (tsp or mL)
under 2 years		ask a doctor
24-35 lbs	2-3 years	1 tsp or 5 mL
36-47 lbs	4-5 years	1 1/2 tsp or 7.5 mL
48-59 lbs	6-8 years	2 tsp or 10 mL
60-71 lbs	9-10 years	2 1/2 tsp or 12.5 mL
72-95 lbs	11 years	3 tsp or 15 mL

Other information each teaspoon contains: sodium 2 mg, store between 20 to 25°C (68° to 77°F). do not use if bottle wrap, or imprinted foil inner seal is broken or missing.

Inactive ingredients acetylsalicylate-potassium, antihydroxy citric acid, D&C yellow #10, FD&C red #40, polyvinyl alcohol bubble gum flavor (E5511, polysorbate 80 (Tween 80), purified water, sodium benzoate, sucrose, xanthan gum.

Questions or Comments? Call 1-877-835-5472, Monday through Friday 9AM - 5PM EST.

PERMANENT GLUE

Ibuprofen
Oral Suspension, USP
 100 mg/5 mL (teaspoon)
 For Ages 2 to 11
Bubble Gum Flavor



Drug Facts (continued)

- 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 (tsp or mL)
under 2 years		ask a doctor
24-35 lbs	2-3 years	1 tsp or 5 mL
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48-59 lbs	6-8 years	2 tsp or 10 mL
60-71 lbs	9-10 years	2 1/2 tsp or 12.5 mL
72-95 lbs	11 years	3 tsp or 15 mL

Other information

- each teaspoon contains: sodium 2 mg
- store between 20° to 25° C (68° to 77° F)
- do not use if bottle wrap, or imprinted foil inner seal is broken or missing
- see bottom panel for lot number and expiration date

Inactive ingredients

acetofenone-potassium, anhydrous citric acid, D&C yellow # 10, FD&C red # 40, glycerin, NA bubble gum flavor FG5511, polyorbate 80 (Ivoren 80), purified water, sodium benzoate, sacrose, xanthan gum

Questions or Comments? Call 1-877-836-6472 Monday through Friday 9AM - 5PM EST.

Keep the carton.

It contains important information. See end panel for expiration date.

*This product is not manufactured or distributed by McNeil-PPC, Inc., distributor of Children's Motrin®.

Distributed by: **Amneal Pharmaceuticals**
 Glasgow, KY 42141

Rev. 07-2011

*Compare to Children's Motrin® active ingredient

SEE NEW WARNINGS INFORMATION

NDC 65162-672-86

For Ages 2 to 11

Ibuprofen
Oral Suspension, USP
 100 mg/5 mL (teaspoon)

Contains **Ibuprofen Oral Suspension (NSAID)**

**Pain Reliever/
 Fever Reducer (NSAID)***

Lasts up to 8 hours

**Bubble Gum
 Flavor**



4 FL OZ (118 mL)

Do not use if imprinted foil inner seal on bottle is broken or missing.



N 3 65162-672-86 2

Lot No.:

Exp. Date:

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 = 1 teaspoon) Purpose
 ibuprofen 100 mg (NSAID)* 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 reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (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 non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
 - takes more or for a longer time 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 any other pain reliever/fever reducer
- right before or after heart surgery

Drug Facts (continued)

Ask a doctor before use if

- child has problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to your child
- child has a history of stomach problems, such as heartburn
- 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, or kidney disease
- 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 or taking any other drug.

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- the child does not get any relief within the 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
- find right dose on chart. If possible, use weight to dose, otherwise use age.
- use only enclosed measuring cup

Creative Design Solutions
 Bethany Matthews
 PROOF 10: 07.14.11 10:00 a.m.

IBUPROFEN PAIN RELIEVER/ FEVER REDUCER

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65162-672
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)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCROSE (UNII: C151H8M554)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color	ORANGE	Score		
Shape		Size		
Flavor	BUBBLE GUM	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-672-86	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA200457	11/12/2011		

Labeler - Amneal Pharmaceuticals (123797875)

Registrant - Amneal Pharmaceuticals (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals		968119730	ANALYSIS, MANUFACTURE, LABEL, PACK