IBUPROFEN ORAL - ibuprofen oral suspension
Strategic Sourcing Services

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

ACTIVE INGREDIENT(S)

(in each 5 mL)
Ibuprofen 100 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

USE(S)

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 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 INGREDIENT SECTION

Berry flavor (with dye)

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.

Berry flavor (dye free)

Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum.

Grape flavor

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.

Bubble Gum flavor

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 SECTION

Call 833-358-6431 Mon - Fri 9 AM to 7 PM EST.

Distributed by: McKesson Corp.,
via Strategic Sourcing Services LLC.,
Memphis, TN 38141

PRINCIPAL DISPLAY PANEL

Ibuprofen oral suspension berry flavour with dye container carton

Ibuprofen oral suspension berry flavour with dye free container carton

Ibuprofen oral suspension grape flavour container carton

Ibuprofen oral suspension bubble gum flavour container carton

IBUPROFEN ORAL

ibuprofen oral suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70677-0150
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CELLULOSE, MICROCRYSTALLINE (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	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0150-1	1 in 1 CARTON	08/01/2022	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70677-0150-2	1 in 1 CARTON	08/01/2022	
2		237 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	11/23/2018	

IBUPROFEN ORAL

ibuprofen oral suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70677-0153
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics			
Color	purple	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70677-0153-1	1 in 1 CARTON	08/01/2022	
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	08/01/2022	

IBUPROFEN ORAL

ibuprofen oral suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70677-0152
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70677-0152-1	1 in 1 CARTON	08/01/2022	
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	08/01/2022	

IBUPROFEN ORAL

ibuprofen oral suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70677-0151
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
CELLULOSE, MICROCRYSTALLINE (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		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0151-1	1 in 1 CARTON	08/01/2022	
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	08/01/2022	

Labeler - Strategic Sourcing Services (116956644)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(70677-0150, 70677-0151, 70677-0152, 70677-0153)

Revised: 8/2022 Strategic Sourcing Services