IBUPROFEN ORAL - ibuprofen oral suspension Strategic Sourcing Services

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

ACTIVE INGREDIENT(S)

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)
- \blacksquare shock \blacksquare skin reddening \blacksquare 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

- 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 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

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	Weight (lb) Age (yr) Dose	Weight (lb) Age (yr) Dose
(mL)*	(mL)*	(mL)*
		under 24 under 2 years ask a
a doctor	a doctor	doctor
24-35 lbs 2-3 years 5 mL	24-35 lbs 2-3 years 5 mL	24-35 lbs 2-3 years 5 mL
36-47 lbs 4-5 years 7.5 mL	36-47 lbs 4-5 years 7.5 mL	36-47 lbs 4-5 years 7.5 mL
48-59 lbs 6-8 years 10 mL	48-59 lbs 6-8 years 10 mL	48-59 lbs 6-8 years 10 mL
60-71 lbs 9-10 years 12.5	60-71 lbs 9-10 years 12.5	60-71 lbs 9-10 years 12.5 mL
mL	mL	
72-95 lbs 11 years 15 mL	72-95 lbs 11 years 15 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

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

QUESTIONS or COMMENTS?

Call 833-358-6431 Monday to Friday 9:00am to 7:00pm EST

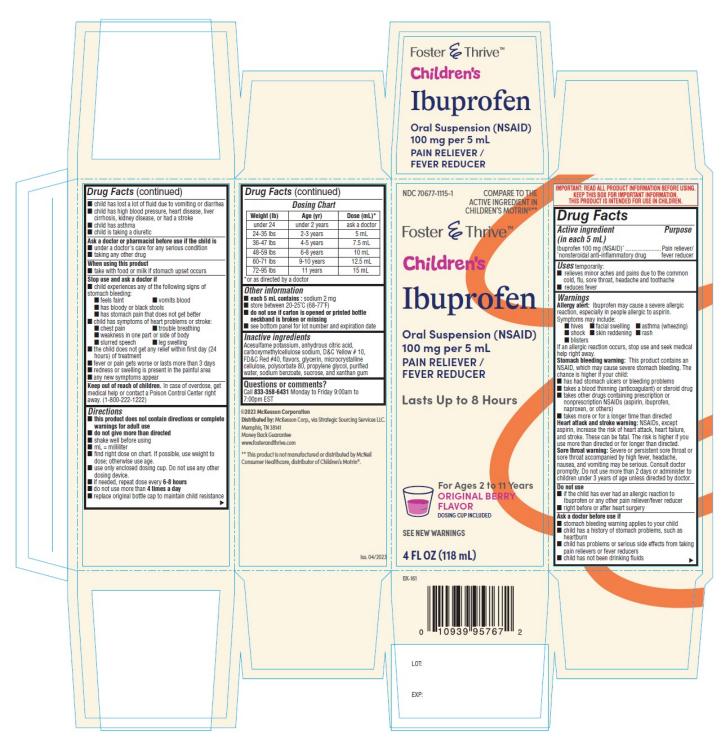
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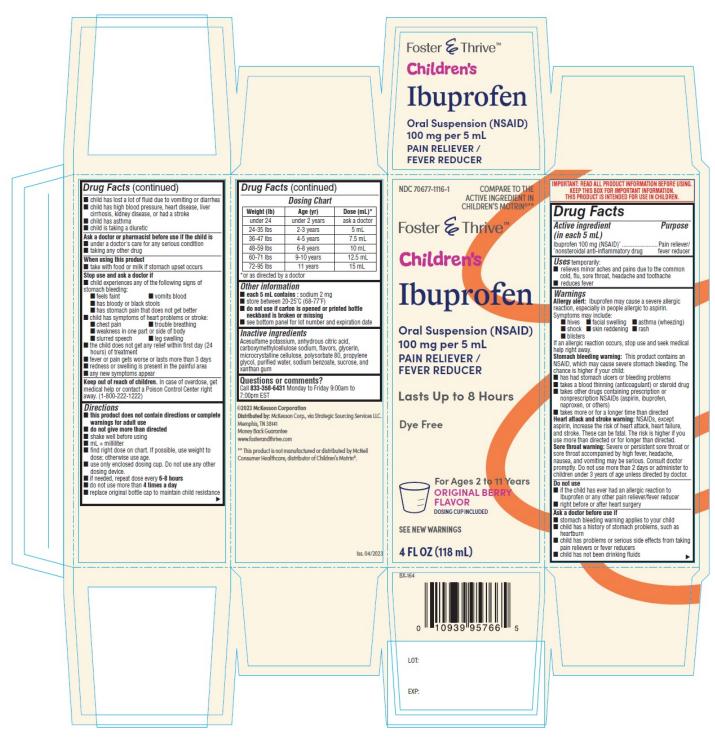
PRINCIPAL DISPLAY PANEL

Ibuprofen oral suspension berry flavor container carton-118 mL

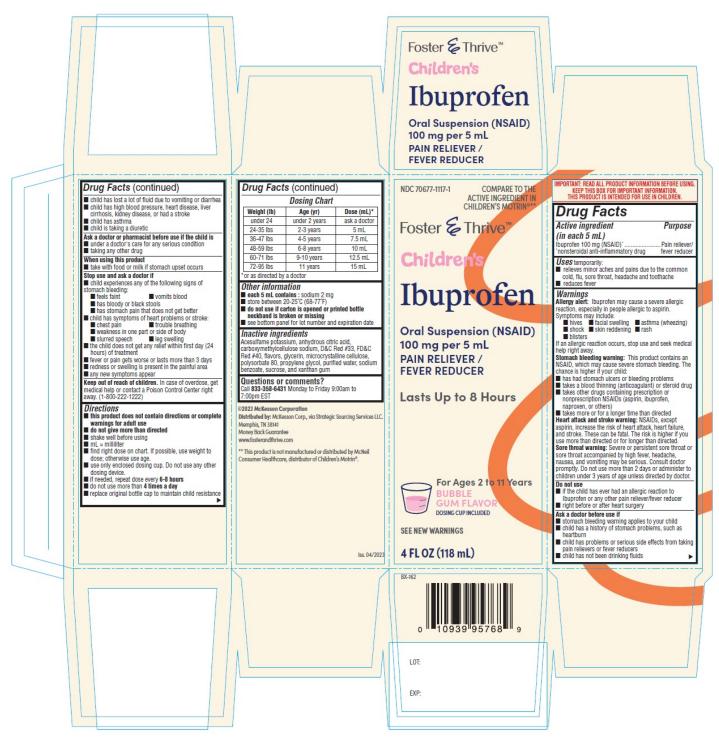
^{**}This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin [®].



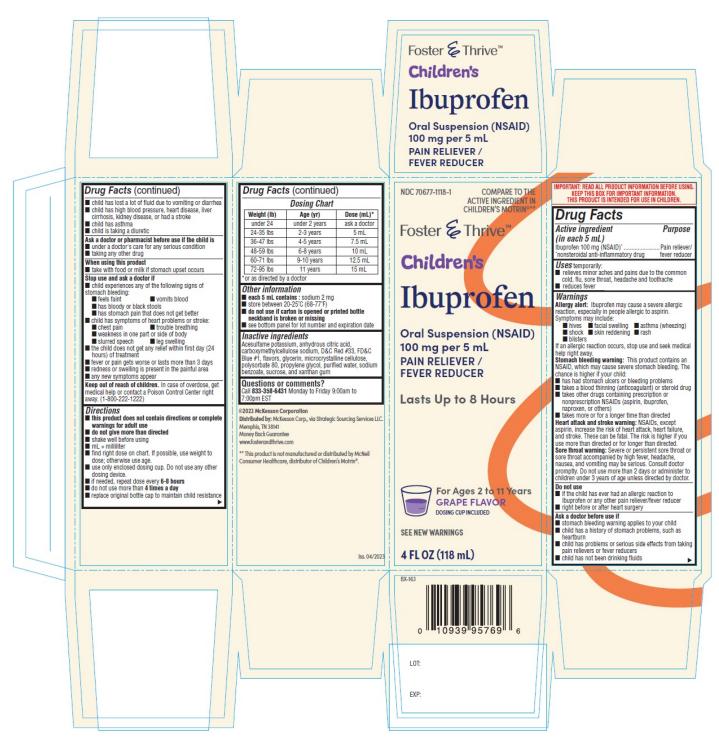
Ibuprofen oral suspension original berry flavor with dye container carton-118 mL



Ibuprofen oral suspension bubble gum flavor container carton-118 mL



Ibuprofen oral suspension grape flavor container carton-118 mL



Ibuprofen oral suspension berry original flavor container carton-237 mL



IBUPROFEN ORAL

ibuprofen oral suspension

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:70677-1115 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: 230V73Q5G9)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
GLYCERIN (UNII: PDC6A3C0OX)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
CELLULOSE, MICROCRYSTALLINE (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	orange	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677- 1115-1	1 in 1 CARTON	08/09/2023	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70677- 1115-2	1 in 1 CARTON	08/09/2023	
2		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date			
ANDA	ANDA210602	08/09/2023	

IBUPROFEN ORAL

ibuprofen oral suspension

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70677-1116

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII: WK2XYI10QM) IBUPROFEN (UNII: WK2XYI10QM) IBUPROFEN 100 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
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	BERRY (original berry flavor)	Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:70677- 1116-1	1 in 1 CARTON	08/09/2023	
1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

ANDA ANDA210602 08/09/2023

IBUPROFEN ORAL

ibuprofen oral suspension

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70677-1117

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: 230V73Q5G9)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)

GLYCERIN (UNII: PDC6A3C0OX)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

POLYSORBATE 80 (UNII: 60ZP39ZG8H)
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- 1117-1	1 in 1 CARTON	08/09/2023	
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	08/09/2023		

IBUPROFEN ORAL

ibuprofen oral suspension

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70677-1118

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: 230V73Q5G9) ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)

GLYCERIN (UNII: PDC6A3COOX)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

POLYSORBATE 80 (UNII: 60ZP39ZG8H)
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		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	

Contains

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:70677- 1118-1	1 in 1 CARTON	08/09/2023		
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product			
	Marketing Information				
M	larketing	intormation			

08/09/2023

Labeler - Strategic Sourcing Services (116956644)

ANDA210602

ANDA

Establishment			
Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(70677-1115, 70677-1116, 70677-1117, 70677-1118)

Strategic Sourcing Services Revised: 8/2023