IBUPROFEN CHILDRENS- ibuprofen suspension FSA Store Inc. (Caring Mills)

Ibuprofen Oral Suspension, USP

Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen, USP 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 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 others drug 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 a 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
 - vomit blood
 - has bloody or black stool
 - 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 (1-800-222-1222) right away.

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 ever 6-8 hours
- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance

Dosing Chart

Weight (lb)	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: 2 mg
- store between 20^o to 25^oC (68^o to 77^oF)

Inactive ingredients

acesulfame potassium, artificial bubble gum flavor, citric acid anhydrous, FD&C red #40, glycerin, polysorbate 80, pregelatinized corn starch, purified water, sodium benzoate, sucrose, xanthan gum

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal display panel

 $+Compare to the active ingredient in Children's Motrin <math display="inline">\ensuremath{\mathbb{R}}$

FOR AGES 2-11 YEARS

CHILDREN'S IBUPROFEN

100 mg per 5 mL

Oral Suspension, USP (NSAID)

PAIN RELIEVER/FEVER REDUCER

BUBBLE GUM FLAVOR

- Shake well before using
- Lasts up to 8 hours
- Alcohol-Free

FL OZ (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®.

TAMPER EVIDENT: DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING.

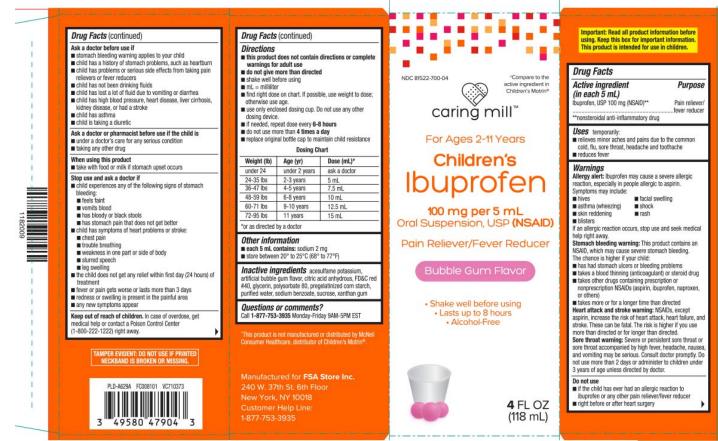
Manufactured for FSA Store Inc.

240 W. 37th St., 6th Floor

New York, NY 10018

Package Label





Caring Mill Childrens Ibuprofen 100 mg Bubble Gum Liquid

IBUPROFEN CHILDP	RENS				
ibuprofen suspension					
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (Source)		NDC:81522-700	
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingredient Name			Basis of Strengt	h Strength	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII: WK2XYI10Q			IBUPROFEN	100 mg in 5 mL	
Inactive Ingredients					
	Ingredient Name			Strength	

Contains							
Flavor	BUBBLE GUM	Imprint Code					
Shape		Size					
Color	pink	Score					
Product Chara	icteristics						
XANTHAN GUM (UN	III: TTV12P4NEE)						
SUCROSE (UNII: C1							
	E (UNII: OJ245FE5EU)						
WATER (UNII: 059Q	F0KO0R)						
STARCH, CORN (UNII: 08232NY3SJ)							
POLYSORBATE 80 (UNII: 60ZP39ZG8H)							
GLYCERIN (UNII: PD	C6A3C0OX)						
FD&C RED NO. 40	(UNII: WZ B9127XOA)						
ANHYDROUS CITRI	C ACID (UNII: XF417D3PSL)						

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:81522-700- 04	1 in 1 CARTON	04/21/2022				
118 mL in 1 BOTTLE; Type 0: Not a Combination Product							
M	arketing	Information					
M	l arketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			

Label	er -	FSA	Store	lnc.	(Caring	Mills)	(049283340)
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Revised: 4/2022

FSA Store Inc. (Caring Mills)