EQUALINE IBUPROFEN CHILDRENS- ibuprofen suspension Supervalu Inc

SuperValu Inc. Ibuprofen Oral Suspension Drug Facts

Active ingredient (in each 5 mL = 1 teaspoonful)

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

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, 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

When using this product

- give 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 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
- 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
- wash dosage cup after each use

Dosing Chart			
Weight (lbs)	Age (yrs)	Dose (teaspoonful 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
- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- · do not freeze
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, natural and artificial bubblegum flavors, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments?

1-877-932-7948

Principal Display Panel

compare to Children's Motrin® active ingredient

for ages 2 to 11

children's

ibuprofen oral suspension

100 mg per 5 mL (teaspoonful)

pain reliever/fever reducer (NSAID)

lasts up to 8 hours

alcohol free

bubble gum flavor



compare to Children's Motrine active ingredient"

children's ibuprofen

oral suspension 100 mg per 5 mL (teaspoonful) pain reliever/fever reducer (NSAID)

equaline°

compare to Children's Motrin® active ingredient**

NDC 41163-166-34

for ages 2 to 11

children's ibuprofen

oral suspension
100 mg per 5 mL (teaspoonful)
pain reliever/
fever reducer
(NSAID)



lasts up to 8 hours

alcohol free



bubble gum flavor

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 Purposes (in each 5 mL = 1 teaspoonful)

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■ under a doctor's care for any serious condition

8 FL. OZ. (240 mL)



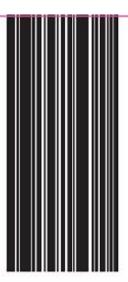
LOT NO.

EXP.

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Drug Facts (continued)

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(Questions or comments? 1-877-932-7948

"This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin®.

GLUTEN FREE

equaline

compare to Children's Motrin® active ingredient

NDC 41163-166-34

for ages 2 to 11

children's

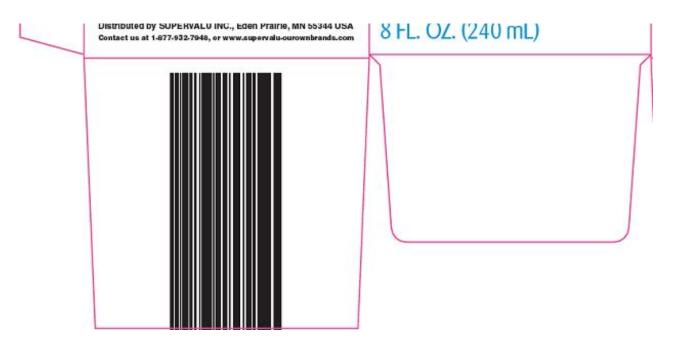
oral suspension 100 mg per 5 mL (teaspoonful) pain reliever/

fever reducer (NSAID)

lasts up to 8 hours · alcohol free



bubble gum flavor



EQUALINE IBUPROFEN CHILDRENS

ibuprofen suspension

XANTHAN GUM

Product Information

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:41163-166Route of AdministrationORALDEA Schedule

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthIBUPROFEN (IBUPROFEN)IBUPROFEN100 mg in 5 mL

Inactive Ingredients Ingredient Name Strength ANHYDROUS CITRIC ACID FD&C RED NO. 40 GLYCERIN HIGH FRUCTOSE CORN SYRUP HYPROMELLOSES POLYSORBATE 80 WATER SODIUM BENZOATE SORBITOL

Product Characteristics				
Color	PINK (light)	Score		
Shape		Size		

Flavor	BUBBLE GUM	Imprint Code
Contains		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-166-26	1 in 1 CARTON		
1		120 mL in 1 BOTTLE		
2	NDC:41163-166-28	1 in 1 CARTON		
2		150 mL in 1 BOTTLE		
3	NDC:41163-166-34	1 in 1 CARTON		
3		240 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA074937	10/07/2004		

Labeler - Supervalu Inc (006961411)

Revised: 10/2012 Supervalu Inc