

**EQUALINE IBUPROFEN CHILDRENS- ibuprofen suspension**  
**Supervalu Inc**

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**SuperValu Inc. Children's Ibuprofen Drug Facts**

**Active ingredient (in each 5 mL = 1 teaspoonful)**

Ibuprofen 100 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purposes**

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 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

- 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, D&C red #33, FD&C blue #1, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, natural and artificial grape flavor, 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® Grape Flavor active ingredient

children's

ibuprofen

oral suspension

100mg per 5mL (teaspoonful)

pain reliever / fever reducer (NSAID)

lasts up to 8 hours

for ages 2 to 11

grape flavor

ALCOHOL FREE

4 FL OZ (118mL)

**EQUALINE®**

children's  
**ibuprofen**

oral suspension  
100mg per 5mL (teaspoonful)

*pain reliever/  
fever reducer  
(NSAID)*

NDC 41163-660-26

compare to  
Children's Motrin®  
Grape Flavor  
active ingredient\*\*

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lasts up to  
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for ages 2 to 11  
**grape flavor**  
ALCOHOL FREE



4 FL OZ (118mL)

**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) 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
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**Warnings**

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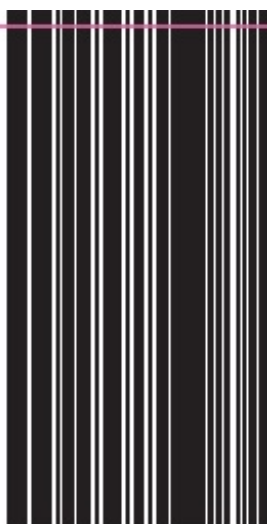
T1E02 (HOME)



LOT NO.

EXP.

: 66026 EL C6



### Drug Facts (continued)

- 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

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  - has bloody or black stools
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### Drug Facts (continued)

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### Questions or comments?

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### GLUTEN FREE

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



We're committed to your satisfaction and guarantee the quality of this product.

Contact us at  
1-877-932-7948, or  
[www.supervalu-ourownbrands.com](http://www.supervalu-ourownbrands.com)  
Please have package available.

Distributed by  
**SUPERVALU INC.**  
Eden Prairie, MN 55344 USA



EQUALINE IBUPROFEN CHILDRENS			
ibuprofen suspension			
Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41163-660
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPROFEN (IBUPROFEN)	IBUPROFEN	100 mg in 5 mL	
Inactive Ingredients			
Ingredient Name		Strength	
ANHYDROUS CITRIC ACID			
D&C RED NO. 33			
FD&C BLUE NO. 1			
FD&C RED NO. 40			
GLYCERIN			
HIGH FRUCTOSE CORN SYRUP			
HYPROMELLOSES			
POLYSORBATE 80			
WATER			
SODIUM BENZOATE			
SORBITOL			
XANTHAN GUM			
Product Characteristics			
Color	PURPLE (opaque)	Score	

Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-660-26	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	ANDA074937		09/24/2004	

**Labeler** - Supervalu Inc (006961411)