

PEDIATRIC DRUG FACTS LABEL
(For Products Labeled Only for Children Under 12 Years of Age)

Drug Facts	
Active ingredient (in each [insert dosage unit])	Purpose
Ibuprofen XXX mg (NSAID)*.....	Pain reliever/fever reducer
* nonsteroidal anti-inflammatory drug	
Uses	
● [add NDA approved uses]	
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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if the child:	
● has had stomach ulcers or bleeding problems	
● takes a blood thinning (anticoagulant) or steroid drug	
● takes other drugs containing an NSAID [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. [<i>For products with an approved "sore throat" indication</i>]	
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 the child has	
● problems or serious side effects from taking pain relievers or fever reducers	
● stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain	
● ulcers	
● bleeding problems	
● not been drinking fluids	
● lost a lot of fluid due to vomiting or diarrhea	
● high blood pressure	
● heart or kidney disease	
● taken a diuretic	

Ask a doctor or pharmacist before use if the child is

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- 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
- long term continuous use may increase the risk of heart attack or stroke

Stop use and ask a doctor if

- the child feels faint, vomits blood, or has bloody or black stools. These are signs of stomach bleeding.
- stomach pain or upset gets worse or lasts
- 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.

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- do not give longer than 10 days, unless directed by a doctor (see Warnings)
- [add NDA approved directions]

Other information

- [storage conditions]

Inactive ingredients [list ingredients in alphabetical order]

Questions or comments? call **1-800-XXX-XXXX**: [insert appropriate times when the phone will be answered by a person, e.g., weekdays 8AM to 11 PM EST; weekends 9AM to 11 PM, EST]