

## ADULT DRUG FACTS LABEL:

<b>Drug Facts</b>	
<b>Active ingredient (in each</b> [insert dosage unit])	<b>Purpose</b>
[insert active ingredient] XXX mg (NSAID)*.....	Pain reliever/fever reducer
* nonsteroidal anti-inflammatory drug	
<b>Uses</b>	
● [add NDA approved uses]	
<b>Warnings</b>	
<b>Allergy alert:</b> [insert active ingredient] 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.	
<b>Stomach bleeding warning:</b> This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you:	
● are age 60 or older	
● have had stomach ulcers or bleeding problems	
● take a blood thinning (anticoagulant) or steroid drug	
● take other drugs containing an NSAID [aspirin, ibuprofen, naproxen, or others]	
● have 3 or more alcoholic drinks every day while using this product	
● take more or for a longer time than directed	
<b>Do not use</b>	
● if you have ever had an allergic reaction to any other pain reliever/fever reducer	
● right before or after heart surgery	
<b>Ask a doctor before use if you have</b>	
● 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	
● high blood pressure	
● heart or kidney disease	
● taken a diuretic	
● reached age 60 or older	
<b>Ask a doctor or pharmacist before use if you are</b>	
● 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**

- you feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts
- redness or swelling is present in the painful area
- any new symptoms appear

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use [*NSAID active ingredient*] during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

***Directions***

- **do not take more than directed**
- **the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- **[add NDA approved direction]**

***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]