

REVIEWED LABELING

Advil Tablets/Caplets/Gel Caplets: Carton (Blister pack - 10 count tablets)

Summary of proposed changes to **Warnings** section of the Drug Facts panel with changes highlighted in red.

New/Revised Warnings	Previous Warnings
<p>Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock Stomach bleeding warning: Taking more than recommended may cause stomach bleeding. Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.</p>	<p>Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.</p>
<p>Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer</p>	<p>Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer</p>
<p>Ask a doctor before use if you have ■ 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 pain ■ ulcers ■ bleeding problems ■ high blood pressure, heart or kidney disease, are taking a diuretic, or are over 65 years of age</p>	<p>Ask a doctor before use if you have had problems or side effects with any pain reliever/fever reducer</p>
<p>Ask a doctor or pharmacist before use if you are ■ under a doctor's care for any serious medical condition ■ taking any other product that contains ibuprofen or any other pain reliever/fever reducer ■ taking a prescription drug for anticoagulation (blood thinning) ■ taking any other drug</p>	<p>Ask a doctor or pharmacist before use if you are ■ under a doctor's care for any continuing medical condition ■ taking other drugs on a regular basis ■ taking any other product containing ibuprofen, or any other pain reliever/fever reducer</p>
<p>When using this product take with food or milk if stomach upset occurs</p>	
<p>Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ pain get 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</p>	<p>Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ fever gets worse or lasts more than 3 days ■ pain gets worse or lasts more than 10 days ■ stomach pain occurs with the use of this product ■ the painful area is red or swollen ■ any new or unexpected symptoms occur</p>