

Other more common side effects reported in patients taking zileuton during clinical trials included headache, upset stomach, abdominal pain and other unspecified pain, and nausea.

Do not take zileuton if:

- You have active liver disease or have liver enzymes that are elevated
- You have ever had an allergic reaction to this drug

What storage conditions are necessary for this drug?

Remember:

- Keep zileuton in the container it came in, tightly sealed.
- Store it away from moisture, heat and direct sunlight. Do not store this medication in the bathroom, near the kitchen sink or in damp places. Store zileuton at room temperature.
- Keep zileuton out of the reach of children.
- Never share your medication with anyone.
- Never take outdated medications. Some medication prescription labels list an expiration date. If such a date is not on your medication label or if you are unsure how old a medication is, call your pharmacy.

When should I call my health care provider?

- Call your doctor immediately if you need more puffs of your bronchodilator inhaler than usual or if you use the maximum number of puffs prescribed for one 24-hour period. This could be a sign of worsening asthma and your asthma therapy may need to be changed.
- Call your doctor immediately if you experience any of the signs or symptoms of elevated liver enzymes, which include right upper quadrant pain, nausea, fatigue, sluggish, itchiness, jaundice (a yellowing of skin color or in the whites of the eyes) flu-like symptoms, or urine that is darker than normal.

This handout summarizes information to help you understand and safely take your medicine. Other information - not included in this handout - might be important for you to know because of your unique health status. Ask your doctor and/or pharmacist for more information on the medicines prescribed for you and your unique health care needs.

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Health Information

What is Zyflo®?

**Head & Neck Institute
Nasal & Sinus Disorders
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What is zileuton (Zyflo®)?

Zileuton is indicated for the prevention and long-term treatment of asthma in adults and children 12 years of age and older. Zileuton is not a bronchodilator and should not be used to treat sudden (e.g., acute) attacks of asthma.

How does zileuton work?

Zileuton blocks the formation of certain chemicals, called leukotrienes, which may contribute to asthma symptoms.

Why is my doctor recommending zileuton?

The biochemical pathways that cause inflammation in the lungs (asthma) and inflammation in the sinuses (chronic rhinosinusitis with and without polyps) are similar. By blocking leukotriene formation, zileuton may reduce sinus inflammation. The FDA has not approved the drug for the treatment of chronic rhinosi-



nusitis with and without polyps; however, some physicians have reported that zileuton seems to help patients with sinusitis and polyps.

How do I take the medication?

Zileuton is taken four times a day. Each tablet contains 600 mg, for a total daily dosage of 2400 mg. The drug can be taken with or without food. For ease of administration, zileuton can be taken with meals and at bedtime. Also, the tablets may be swallowed whole or split in half to make them easier to swallow.

What special instructions should I follow while using this drug?

- Zileuton must be taken every day as prescribed by your doctor. Do not decrease the dose or stop taking the drug without talking to your doctor first. Feeling good is a sign that the medication is working.
- Make sure that you return to your doctor's office for scheduled liver enzyme tests. Liver enzymes are measured in a simple blood test. The enzymes are measured to make sure they don't become too high so that it is safe for you to continue to take zileuton. Sometimes liver enzymes become elevated without you noticing any symptoms. This is

why it is important for your liver enzymes to be checked at the start of therapy and regularly while you are taking zileuton.

- Understand that it may take several days or a few weeks to get the full benefit from zileuton, therefore do not stop taking the drug if you do not feel better right away.
- Understand that zileuton will not relieve an asthma attack that has already started. Remember to continue to take your other asthma medications as directed by your doctor.
- Never take a larger dose of zileuton or take it more often than prescribed by your doctor.

What special precautions should I follow before using this drug?

- Tell your doctor if you are taking theophylline for asthma, the blood-thinning drug warfarin, or the



blood pressure lowering drug propranolol - the dosages of these medications may need to be changed. Also inform your doctor of all other medications you are taking, including vitamins, herbals, dietary supplements, and other prescription and nonprescription (over-the-counter) medications. Your doctor will determine if a dose adjustment (or discontinuation) is necessary in any of these products while you are taking zileuton.

- Tell your doctor if you have ever had liver disease, hepatitis, jaundice (a yellowing of your eyes or skin) or dark urine.
- Tell your doctor if you drink alcohol.
- Tell your doctor if you are pregnant, planning to become pregnant, or are breast-feeding.

What are the side effects of this drug?

The most serious side effect of zileuton is an elevation of liver enzymes. Your doctor should check your liver enzyme levels at the start of zileuton therapy and on a regular basis while you are taking this drug.