

## **17.2 FDA-Approved Patient Labeling**

### **Zileuton (zye loo' ton) Extended-Release Tablets**

Read the Patient Information that comes with zileuton extended-release tablets carefully before you start taking it and read it each time you get a refill. There may be new information. This leaflet does not take the place of talking with your health care provider about your medical condition or your treatment.

#### **What is Zileuton Extended-Release Tablet?**

Zileuton extended-release tablet is a medicine that is used to prevent asthma attacks and for long-term management of asthma in adults and children 12 years of age and older. Zileuton extended-release tablet blocks the production of leukotrienes. Leukotrienes are substances that may contribute to your asthma.

Zileuton extended-release tablet is not a rescue medicine (it is not a bronchodilator) and should not be used if you need relief right away for an asthma attack.

#### **Who should not take Zileuton Extended-Release Tablets?**

Do not take zileuton extended-release tablets if you have:

- active liver disease or repeated blood tests showing elevated liver enzymes (substances released by the liver).
- ever had an allergic reaction to zileuton extended-release tablets or any of the ingredients in zileuton extended-release tablets.

#### **What should I tell my health care provider before taking Zileuton Extended-Release Tablets?**

Zileuton Extended-Release Tablets may not be right for you. Tell your health care provider if you:

- have ever had liver problems, including hepatitis, jaundice (yellow eyes or skin), or dark urine.
- drink alcohol. Tell your health care provider how much and how often you drink alcohol.
- have difficulty swallowing pills.
- are pregnant or planning to become pregnant. It is not known if zileuton extended-release tablets will harm your unborn baby. Do not take zileuton extended-release tablets during pregnancy unless you and your health care provider decide that taking the medicine is more important than the possible risk to your unborn baby.
- are breastfeeding. It is not known if zileuton passes into your breast milk. You and your health care provider should decide if you will take zileuton extended-release tablets or breast feed. You should not do both.

**Tell your health care provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Zileuton extended-release tablets and other medicines may affect each other causing side effects. Your health care provider may need to adjust the doses of certain medicines while you are taking zileuton extended-release tablets. Talk with your health care provider before starting or stopping any prescription or nonprescription medicine.

Know the medicines you take. Keep a list of your medicines and show it to your health care provider and pharmacist when you get a new medicine.

### **How should I take Zileuton Extended-Release Tablets?**

- Take zileuton extended-release tablets exactly as prescribed by your health care provider. Do not decrease the dose of zileuton extended-release tablets or stop taking the medicine without talking to your health care provider first, even if you have no asthma symptoms.
- Take two zileuton extended-release tablets two times each day within one hour after your morning and evening meals.
- Swallow zileuton extended-release tablets whole. **Do not chew, cut or crush zileuton extended-release tablets.** Tell your health care provider if you cannot swallow the tablets whole.
- Follow your health care provider's instructions for what to do if you get sudden symptoms of an asthma attack. You can continue taking zileuton extended-release tablets during asthma attacks.
- Get medical help right away if you need to use your rescue medicine more often than usual or if you use the highest number of "puffs" prescribed for one 24-hour period. These could be signs that your asthma is getting worse. This means that your asthma therapy may need to be changed.
- Keep taking your other asthma medicines as directed while taking zileuton extended-release tablets.
- If you miss a dose, just take your next scheduled dose when it is due. Do not double the dose.
- If you take too much zileuton extended-release tablets, call your health care provider or a Poison Control Center right away.

### **What are the possible side effects of Zileuton Extended-Release Tablets?**

Zileuton extended-release tablets can cause serious side effects.

**Liver problems.** Liver function enzymes and bilirubin can increase while taking zileuton extended-release tablets, and severe liver injury can occur.

Sleep disorders and changes in your behavior can happen while you take zileuton extended-release tablets. Tell your healthcare provider if you have any sleep problems or changes in behavior.

- Keep all of your health care provider's appointments and be sure to follow all of your health care provider's instructions. Have your blood tests done as ordered to check your liver enzymes.
- Tell your health care provider right away if you get any of the following signs or symptoms: pain on the right side of your abdomen (stomach area), nausea, tiredness, lack of energy, itching, yellow skin or yellow color in the whites of your eyes, dark urine, or "flu-like" symptoms.

Some of the most common side effects are:

- nose and throat irritation
- sinusitis
- upper respiratory infection
- throat pain
- headache
- muscle aches

- nausea
- diarrhea

Allergic reactions can happen while taking zileuton extended-release tablets. Tell your health care provider right away if you get any of the following signs or symptoms: rash or hives.

Tell your health care provider if you have any new or unusual symptoms that bother you or do not go away while taking zileuton extended-release tablets.

These are not all of the possible side effects of zileuton extended-release tablets. For more information, ask your health care provider or pharmacist.

### **How should I store Zileuton Extended-Release Tablets?**

- Store zileuton extended-release tablets between 68°F and 77°F (20°C to 25°C).
- Protect zileuton extended-release tablets from light and replace the cap each time after use.

**Keep Zileuton Extended-Release Tablets and all medicines out of the reach of children.**

### **General Information about Zileuton Extended-Release Tablets:**

Medicines are sometimes prescribed for conditions that are not mentioned in the patient leaflet. Do not use zileuton extended-release tablets for a condition for which it was not prescribed. Do not give zileuton extended-release tablets to other people, even if they have the same symptoms you have. It may harm them.

This patient information leaflet summarizes the most important information about zileuton extended-release tablets. If you would like more information about zileuton extended-release tablets, talk with your health care provider or pharmacist. You can ask your health care provider or pharmacist for information about zileuton extended-release tablets that is written for health professionals.

For more information, go to [www.lupinpharmaceuticals.com](http://www.lupinpharmaceuticals.com) website or call 1-800-399-2561.

### **What are the ingredients in Zileuton Extended-Release Tablets?**

**Active ingredient:** zileuton

**Inactive ingredients:** crospovidone, hydroxypropyl cellulose, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, povidone, polyethylene glycol, pregelatinised starch.

Manufactured for:  
**Lupin Pharmaceuticals, Inc.**  
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Manufactured by:  
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