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Zileuton

pronounced as (zye loo' ton)

Why is this medication prescribed?

Zileuton is used to prevent wheezing, shortness of breath, coughing, and chest tightness due to asthma. Zileuton is not used to treat an asthma attack (sudden episode of shortness of breath, wheezing, and coughing) that has already started. Zileuton belongs to a class of medications called leukotriene synthesis inhibitors. It works by stopping the formation of certain natural substances that cause swelling, tightening, and mucus production in the airways.

How should this medicine be used?

Zileuton comes as a tablet and an extended-release (long-acting) tablet to take by mouth. The tablet is usually taken four times a day with or without food. The extended-release tablet is usually taken twice a day, within one hour after the morning and evening meals. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take zileuton exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the extended-release tablets whole. Do not split, chew, or crush them.

Do not use zileuton to treat a sudden asthma attack. Your doctor will prescribe a short-acting inhaler to use during attacks. Talk to your doctor about how to treat symptoms of a sudden asthma attack.

Continue to take all other medications that your doctor has prescribed to treat your asthma. Do not stop taking any of your medications or change the doses of any of your medications unless your doctor tells you that you should.

Tell your doctor if your asthma worsens during your treatment. Call your doctor if you need to use more of your fast-acting medication than usual or if you need to use the maximum number of doses of your fast-acting medication.

Zileuton helps control asthma symptoms but does not cure asthma. It may take several days or longer before you feel the full benefit of zileuton. Continue to take zileuton even if you feel well. Do not stop taking zileuton without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses. Ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking zileuton,

- tell your doctor and pharmacist if you are allergic to zileuton or any other medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin); antifungals such as itraconazole (Sporanox) and ketoconazole (Nizoral); beta blockers such as atenolol (Tenormin), labetalol (Trandate), metoprolol (Lopressor, Toprol XL), nadolol (Corgard), and propranolol (Inderal); calcium channel blockers such as amlodipine (Norvasc), felodipine, isradipine (DynaCirc), nifedipine (Cardene), nifedipine (Adalat, Procardia), nimodipine, and nisoldipine (Sular); cisapride (Propulsid); clarithromycin (Biaxin); cyclosporine (Gengraf, Neoral, Sandimmune); HIV protease inhibitors such as atazanavir (Reyataz), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); nefazodone; telithromycin (Ketek); and theophylline (Theo-24, Uniphyll). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have liver disease. Your doctor will probably tell you not to take zileuton.
- tell your doctor if you have difficulty swallowing pills, if you drink or have ever drunk large amounts of alcohol, and if you had liver disease in the past but recovered.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking zileuton, call your doctor.
- ask your doctor about the safe use of alcohol while you are taking zileuton.
- you should know that your mental health may change in unexpected ways while you are taking zileuton. You should call your doctor right away if you experience any of the following symptoms: agitation, aggressive behavior, anxiety, irritability, unusual dreams, hallucinations (seeing things or hearing voices that do not exist), depression, difficulty falling asleep or staying sleep, restlessness, suicidal behavior (thinking about harming or killing yourself or planning or trying to do so), or tremor (uncontrollable shaking of a part of the body). Your doctor will decide if you should continue taking zileuton.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your regular diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Zileuton may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away.

- headache
- heartburn
- diarrhea
- muscle pain
- nose and throat irritation
- pain or fullness in the face

Some side effects can be serious. If you experience any of the following symptoms or those listed in the SPECIAL PRECAUTIONS section, call your doctor immediately.

- rash
- hives
- pain in the upper right part of the stomach
- nausea
- vomiting
- excessive tiredness
- itching
- yellowing of the skin or eyes
- dark urine
- flu-like symptoms

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

Zileuton may cause other side effects. Call your doctor if you experience any unusual problems while you are taking this medication.

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps

and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before and during your treatment.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Zylflo[®]
- Zylflo[®] CR

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