The NH during therapy with Zileuton Extended-Release Tablets.

Zileuton Extended-Release Tablets are not indicated for the treatment of patients with asthma.

Indications and Usage

Zileuton Extended-Release Tablets are indicated for the prophylaxis and treatment of asthma in adults and children 12 years of age and older.

Warnings and Precautions

- A history of allergic reaction to zileuton or any of the ingredients of Zileuton Extended Release Tablets (e.g., lactose).
- Rash, eosinophilia, etc.

Nursing Mothers

Zileuton and/or its metabolites are excreted in rat milk. It is not known if Zileuton or its metabolites are excreted in human milk. Because breastfed infants may be exposed to Zileuton or its metabolites, women should not breastfeed if they are taking Zileuton Extended-Release Tablets.

Other Concomitant Drug Therapy

- Zileuton is a potent inhibitor of the cytochrome P450 3A4 enzyme system.
- Coadministration of zileuton with cytochrome P450 3A4 substrates may result in increased plasma levels of the substrate.

Drug Interactions

- Zileuton may increase the plasma levels of theophylline by 52%. It is recommended to monitor the plasma levels of theophylline in patients taking zileuton and to adjust the theophylline dosage if necessary.

Dosage and Administration

- Zileuton Extended-Release Tablets are not recommended for patients with moderate to severe hepatic impairment.
- The use of Zileuton Extended-Release Tablets is contraindicated in patients with active liver disease.

Patient Counseling Information

- Tell your health care provider before taking Zileuton Extended-Release Tablets.
- If you have ever had an allergic reaction to Zileuton Extended-Release Tablets or any of the ingredients in Zileuton Extended-Release Tablets.
- Do not take Zileuton Extended-Release Tablets.
- 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 risks to your unborn baby.
- Breastfeeding: It is not known if Zileuton Extended-Release Tablets passes into your breast milk. You and your health care provider should decide if you will take Zileuton Extended-Release Tablets while you are breastfeeding.

How should I take Zileuton Extended-Release Tablets?

- Take Zileuton Extended-Release Tablets exactly as prescribed by your health care provider.
- Do not exceed the dose of Zileuton Extended-Release Tablets without talking to your health care provider.
- Tell your health care provider if you have had an adverse reaction to Zileuton Extended-Release Tablets.
- Tell your health care provider if you have ever had liver problems, including hepatitis, jaundice (yellow-tinged skin), or jaundice.

Adverse Reactions

- The most commonly reported adverse reactions (occurring at a frequency of >5%) in Zileuton Extended-Release Tablets group were rash, rhinitis, sinusitis, and nasopharyngitis.
- Other commonly observed adverse reactions include injection site reactions, fever, dizziness, and headache.

Pharmacokinetics

- Zileuton is an inhibitor of 5-lipoxygenase and thus prevents the synthesis of leukotrienes.
- Zileuton is metabolized by the cytochrome P450 3A4 enzyme system.

How should I store Zileuton Extended-Release Tablets?

- Store Zileuton Extended-Release Tablets at room temperature.
- Keep Zileuton Extended-Release Tablets out of the reach of children.
- Do not use Zileuton Extended-Release Tablets beyond the expiration date.

What is Zileuton Extended-Release Tablets?

Zileuton Extended-Release Tablets are a leukotriene synthesis inhibitor indicated for the prophylaxis and treatment of asthma in adults and children 12 years of age and older.

Mechanism of Action

Zileuton is an inhibitor of 5-lipoxygenase and thus prevents the synthesis of leukotrienes.

References


Further information

- For more information, please visit the Zileuton Extended-Release Tablets website or contact your health care provider.

PATIENT INSTRUCTIONS SHEET (PIS)

Zileuton 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 more 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 Tablets?

Zileuton Extended-Release Tablets is a medicine that is used to prevent asthma attacks and to help control asthma symptoms in adults and children 12 years of age and older. Zileuton Extended-Release Tablets blocks the production of leukotrienes. Leukotrienes are chemicals that contribute to your asthma.

Zileuton Extended-Release Tablets 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.

If you have any questions, please contact your health care provider. If you change your medication, please let your health care provider know.

Who should not take Zileuton Extended-Release Tablets?

- Do not take Zileuton Extended-Release Tablets if you:
  - have ever had liver problems, including hepatitis, jaundice (yellow-tinged skin), or jaundice.
  - have difficulty swallowing pills.
  - are pregnant or nursing or plan to become pregnant or nursing.
  - have had an allergic reaction to Zileuton Extended-Release Tablets or any of the ingredients in Zileuton Extended-Release Tablets.
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What should I tell my health care provider before taking Zileuton Extended-Release Tablets?

- Tell your health care provider if you:
  - have ever had liver problems, including hepatitis, jaundice (yellow-tinged skin), or jaundice.
  - have difficulty swallowing pills.
  - are pregnant or nursing or plan to become pregnant or nursing.
  - have had an allergic reaction to Zileuton Extended-Release Tablets or any of the ingredients in Zileuton Extended-Release Tablets.
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How should I take Zileuton Extended-Release Tablets?

- Take Zileuton Extended-Release Tablets exactly as prescribed by your health care provider.
- Do not exceed the dose of Zileuton Extended-Release Tablets without talking to your health care provider.
- If you have no more medicine, please contact your health care provider.
- If you have any questions, please contact your health care provider.

If you get any new symptoms, please contact your health care provider. If you get what you think is an allergic reaction to Zileuton Extended-Release Tablets, please contact your health care provider immediately. If you get stomach pain, vomiting, or diarrhea, please contact your health care provider immediately.

If you have any questions, please contact your health care provider. If you change your medication, please let your health care provider know.

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At steady state, relative unscheduled DNA synthesis rising pharmaceuticals. Inc. manufactured for: manufactured by:

Starch, polyethylene glycol 400, sodium lauryl sulfate, sodium mannitol, microcrystalline cellulose, partially pregelatinized maize.

Tell your health care provider if you have any new or unusual symptoms that bother you or if you 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 at controlled room temperature, 20 to 25°C (68° to 77°F) (see USP . Protect from light.

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Hepatic Impairment

The pharmacokinetics of zileuton immediate-release tablets were similar in healthy elderly subjects (>65 years) compared to healthy subjects (ages 65 to 81 years, 9 males, 9 females) and healthy young subjects (ages 18 to 50 years, 10 males, 9 females). The mean (% C vs. healthy subjects) was 0.36 (90% CI: 0.30, 0.43), 0.35 (90% CI: 0.29, 0.42), and 0.34 (90% CI: 0.28, 0.40) for CL , AUMC , and AUC , respectively. The mean (% C vs. healthy subjects) was 1.09 (90% CI: 0.95, 1.24), 1.19 (90% CI: 1.05, 1.34), and 1.25 (90% CI: 1.11, 1.40) for CL , AUMC , and AUC , respectively.

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