

Medication Guide

Zonisamide Capsules

Read this Medication Guide before you start taking zonisamide and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about zonisamide?

1. Zonisamide may cause a serious skin rash that can cause death. These serious skin reactions are more likely to happen when you begin taking zonisamide within the first 4 months of treatment but may occur at later times.
2. Zonisamide may cause you to sweat less and to increase your body temperature (fever). You may need to be hospitalized for this. You should watch for decreased sweating and fever, especially when it is hot and especially in children taking zonisamide.

Call your health care provider right away if you have:

- **a skin rash**
 - **fever**
 - **less sweat than normal**
3. **Zonisamide can cause blood cell abnormalities such as reduced red and white blood cell counts.** Call your healthcare provider if you develop fever, sore throat, sores in your mouth, or unusual bruising.
 4. **Like other antiepileptic drugs, zonisamide may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempt to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

Do not stop zonisamide without first talking to a healthcare provider.

- Stopping zonisamide suddenly can cause serious problems.

- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

What is zonisamide?

Zonisamide is a prescription medicine that is used with other medicines to treat partial seizures in adults.

It is not known if zonisamide is safe or effective in children under 16 years of age.

Who should not take zonisamide?

Do not take zonisamide if you are allergic to medicines that contain sulfa.

What should I tell my healthcare provider before taking zonisamide

Before taking zonisamide, tell your healthcare provider about all your medical conditions, including if you:

- have or have had depression, mood problems or suicidal thoughts or behavior
- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant. You and your healthcare provider will have to decide if you should take zonisamide while you are pregnant. If you become pregnant while taking zonisamide, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
- are breastfeeding. It is not known if zonisamide passes into breast milk and if it can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take zonisamide.

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins or herbal supplements. Zonisamide and other medicines may affect each other causing side effects.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist each time you get a new medicine.

How should I take zonisamide?

- Take zonisamide exactly as prescribed. Your healthcare prescriber may change your dose. Your healthcare provider will tell you how much zonisamide to take.
- Take zonisamide with or without food.
- Swallow the capsules whole.
- If you take too much zonisamide, call your local Poison Control Center or go to the nearest emergency room right away.
- Do not stop taking zonisamide without talking to your healthcare provider. Stopping zonisamide suddenly can cause serious problems, including seizures that will not stop (status epilepticus).
- Do not drive a car, work with machines, or do other dangerous activities until you know how zonisamide affects you. Zonisamide may make you drowsy.

What are the possible side effects of zonisamide?

Zonisamide can cause serious side effects including:

- the side effects mentioned above (see “What is the most important information I should know about zonisamide?”)
- **worsening seizures**
- **kidney stones** (sudden back pain, stomach pain, or blood in your urine)
- **problems with mood or thinking** (new or worse depression; sudden changes in mood, behavior, or loss of contact with reality, sometimes associated with hearing voices or seeing things that are not really there; feeling sleepy or tired; trouble concentrating; speech and language problems)

Call your healthcare provider right away if you have any of the symptoms listed above.

The most common side effects of zonisamide include:

- drowsiness
- loss of appetite
- dizziness
- trouble with walking and coordination
- headache
- nausea
- agitation
- irritability

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all of the possible side effects of zonisamide. For more information, ask your healthcare provider or pharmacist.

Can your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store zonisamide?

Store at 25°C (77°F), excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature.] Store in a dry place and protect from light.

Keep zonisamide and all medicines out of the reach of children.

General Information about the safe and effective use of zonisamide

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use zonisamide for a condition for which it was not prescribed. Do not give zonisamide to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about zonisamide. IF you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about zonisamide that is written for health professionals.

For more information, go to www.glenmarkgenerics.com or call 1 (888)721-7115.

What are the ingredients in zonisamide?

Active ingredient: zonisamide

Inactive ingredients: microcrystalline cellulose, hydrogenated vegetable oil, sodium lauryl sulfate, gelatin and colorants.

The printed capsule shell of the different strengths is made from the following ingredients:

25 mg - D&C Red #28, FD&C Blue #1, gelatin and titanium dioxide

50 mg - D&C Yellow #10, FD&C Blue #1, FD&C Red #40, gelatin and titanium dioxide

100 mg - D&C Yellow #10, FD&C Blue #1, FD&C Yellow #6, gelatin and titanium dioxide

The dyes used in the printing ink are FD&C Blue #1, FD&C Blue #2, FD&C Red #40, D&C Yellow #10 aluminium lake and iron oxide black. Additionally, the printing ink also contains n-butyl alcohol, ethanol, methanol, propylene glycol and shellac.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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March 2010