

Patient Name: _____ Date: _____
Doctor Name: _____ Emergency Phone Number: _____
Pharmacy: _____ Number: _____

What is Zonisamide?

Zonisamide has been approved by the Food and Drug Administration to treat partial seizures in adults with epilepsy. It is intended to be used along with other seizure medicines.

- Zonisamide is available in generic form and may look different than the brand name drug.
- The dose of zonisamide and how it is taken may vary depending on the form of medicine, why it is prescribed, and whether it is taken alone or with other medicines. It is important to follow the exact directions given to you by your doctor.
- Do not take zonisamide if you are allergic to sulfa drugs.
- Always check the appearance of the capsules with the pharmacist when the prescription is filled to be certain you are given the right medication.

Important questions to ask your doctor:

- Why am I being given this medicine? _____
- What amount should I be taking? _____

What does the drug look like and how should I take it?

Zonegran® Capsules:

25 mg (white with white cap)
Marked with company logo and "Zonegran 25"

50 mg (white with gray cap)
Marked with company logo and "Zonegran 50"

100 mg (white with red cap)
Marked with company logo and "Zonegran 100"



To take capsules:

- Swallow whole with a full glass of water.
- Usually taken once or twice a day.

Frequently asked questions:

Is it best to take this medicine with food? This medicine can be taken with or without food. Try to take it the same way each day, since taking this with food may change the time it takes to be absorbed.

What should I do if I miss a dose? If you miss or forget a dose take it as soon as possible. However, if you have missed a dose and it is within a few hours of your next dose, take only the next scheduled dose. Do not double up or take extra medicine, unless instructed to do so by your doctor.

How can I remember to take my medicine?

- Take medicine at the same time each day.
- Take at the same time as some other routine, such as brushing teeth, after meals, or bedtime.
- Use a pillbox so you can check if you have taken a dose.
- Use an alarm to remind you of times to take a dose.
- Keep a written schedule or chart of when to take the medicine.
- Talk to your doctor or health care provider about problems remembering the medicine.

How long will it take for the medicine to work? It may take a number of weeks or months to find the right dose, and then more time may be needed to know how well the medicine works to control your seizures. How long this takes will be different for each person. It may depend on how often you have seizures, what other medicine you may be taking, and how your body responds to the drug.

Should I write down how the medicine is affecting me? It is important to write down how you feel while you are on the medicine. Also keep track of changes in how much medicine is prescribed, side effects, and changes in seizures. Take the information to all follow-up visits with your health care providers.

How should I store my medicine? Store the medicine at room temperature (25°C or 77°F), away from heat, moisture, and direct light. Keep all medicine out of reach of children. Don't keep it in the bathroom, glove box of a car, or where children can easily find them, such as in purses, on low cabinets or on counter tops for example.

Will this medicine affect other medicines that I am taking? Make sure to tell all your health care providers the names of all medicines, herbal or dietary supplements, vitamins, and over-the-counter medicines you are taking. Some of these medicines may interfere with how zonisamide works and lower or raise the amount in your system. This medicine may also affect how other medicines work.

Some medicines that may interact with zonisamide include: oral contraceptives and other antiepileptic medications. Please see AED Interaction Sheets for list of other medicines that may interact with zonisamide.
(<http://professionals.epilepsy.com/pdfs/epilepsy-zonisamide-912.pdf>).

What side effects may occur? Side effects may occur with any medicine. Some will go away on their own or when the dose of medicine is changed. Others may be more serious and mean that your body is not tolerating the drug. Tell your doctor about all side effects that occur, but do not stop taking the medicine without advice from your doctor. Some side effects include the following:

Common: Headache, dizziness, tired, sleepy, double vision, weight loss, irritable, upset stomach.

Less Common: Confusion, difficulty concentrating, poor coordination, tremors or shaking movements, changes in blood concentrations of glucose (sugar) and sodium, abnormalities of liver function tests.

Potentially serious side effects:

- **Rash:** Not all rashes are caused by the medicine, but all rashes should be immediately reported to your doctor and checked out. Rashes that may be more serious usually begin in the first few weeks, but can happen at any time while you are on the drug. Serious rashes may have the following symptoms and require immediate evaluation:
 - Blisters or sores in the mouth, eyes, ears, nose, and genital area.
 - Swelling of eyelids or red eyes.
 - Red spots or patches on the skin.
 - Fever or flu-like symptoms that do not go away.
- **Kidney stones:** Most likely to occur in people with a family history of kidney stones, who had kidney stones before, who are taking acetazolamide or topiramate, or who are using the ketogenic diet. Symptoms of kidney stones may include: sharp pains in the side or lower back, blood in urine, or difficulty urinating.
- **Inadequate sweating:** Some children who take zonisamide may not sweat enough in hot weather and their body temperatures may rise, sometimes to dangerous levels. Children taking zonisamide should be checked in hot weather to be sure they sweat appropriately.
- **Changes in mood or behavior:** Some patients taking zonisamide have become depressed, sometimes severely. Some children may show changes in their behavior.

- **Allergic reaction:** May be seen with symptoms such as hives or large red spots on the body, itching, difficulty breathing or closing of the throat.

How can I manage side effects?

- To help lessen upset stomach, take the medicine with a snack or meal.
- To help lessen dizziness or tiredness, take the medicine before bedtime.
- To help prevent kidney stones, drink plenty of water, juice or other liquids.
- Some side effects improve over time. If a side effect is difficult to manage or doesn't go away, talk to your doctor.

When should I call my doctor?

- Call your doctor right away if any side effects are severe or cause problems in your ability to function, or if you have any of the following problems while taking the medicine: staggering walk, rash, blood in urine, sudden back pain, or allergic reaction.
- Do not stop the medicine without talking to your doctor first.

Can this seizure medicine affect bone health? Some seizure medicines may cause thinning of the bones. While zonisamide is not known to cause bone problems, all people taking seizure medicine should take calcium and vitamin D supplements each day. Regular exercise and a healthy diet are also very important. People who have thinning of the bones may also need prescription medicine to treat this. Talk to your doctor about how to check the health of your bones and what to do next.

Can I drink alcohol while on this medicine? People taking this medicine should not drink alcohol, because zonisamide may increase the effects of alcohol.

May I drive while taking zonisamide? Use caution when driving, operating machinery, or performing other hazardous activities. This medicine may cause dizziness and drowsiness. If you have these problems or are having seizures, avoid these activities and talk to your doctor.

Just for Women:

Is this medicine safe to take during pregnancy? Zonisamide has an FDA pregnancy category of "C" meaning that the benefits of the medicine may outweigh the risks of harming the fetus. If you find or suspect that you may be pregnant, continue taking the medicine and contact your doctor right away. Talk to your doctor about the potential benefits and risks before making any decisions about use of this medicine. Seizures can be harmful to the mother and developing baby, but these can be lessened with proper care.

Does this medicine affect birth control pills? This medicine does not appear to affect hormonal contraceptives or birth control. However, talk to your doctor if you start or stop any hormonal birth control while taking this medicine, because it may affect the level of zonisamide in your body. Other forms of birth control, such as barrier methods, may be suggested. Call your doctor if you have any signs of breakthrough bleeding or symptoms of pregnancy.

Will the medicine affect my menstrual cycle? This medicine should not affect the menstrual cycle. If your cycle becomes irregular, call your doctor.

Can I breast feed while taking this medicine? In general, women taking zonisamide can breastfeed while using this medicine. However, the drug does pass through breast milk in small amounts. According to the American Academy of Neurology, the benefits for the infant and mother are believed to outweigh the risk for adverse effects. Talk to your doctor about all your options.

Are there any specific vitamins I should be taking? All women who could possibly get pregnant should take at least 0.4 milligrams (mg) of folic acid or folate each day. Doctors may recommend that women with epilepsy taking seizure medicine take a higher dose of folic acid, up to 4 mg a day. Speak to your health care provider for specific instructions. Folic acid is also found in leafy dark green vegetables, fruits and juices, and lentils.

More questions?

For more detailed information about zonisamide please visit www.epilepsy.com and click on Treatment >> Seizure Medicines (www.epilepsy.com/epilepsy/seizure_medicines.html).

May 2007. Lindsay Sutter, PharmD Candidate, Barry E. Gidal, PharmD, University of Wisconsin-Madison; Patricia O. Shafer RN, MN, Epilepsy TDP.

On July 10, 2008, an advisory panel was convened by the Food and Drug Administration (FDA) to review data that the FDA had previously collected from drug studies showing an association between many of the antiepileptic drugs (AEDs) and suicidal ideation and behavior, which together are called suicidality. According to the FDA's Alert, among the patients with epilepsy in these drug studies, 1 out of 1000 people taking the placebo (inactive substance) showed suicidality compared to approximately 3.5 out of 1000 people who took an AED. The FDA advisory panel voted to accept the FDA's data at its meeting on July 10.

The FDA has provided the following information for patients, family members, and caregivers at www.fda.gov/cder/drug/InfoSheets/HCP/antiepilepticsHCP.htm:

- Taking antiepileptic medicines may increase the risk of having suicidal thoughts or actions;
- Do not make any changes to the medication regimen without first talking with the responsible healthcare professional;
- Pay close attention to any day-to-day changes in mood, behavior and actions. These changes can happen very quickly so it is important to be mindful of any sudden differences.
- Be aware of common warning signs that might be a signal for risk of suicide. Some of these are:
 - Talking or thinking about wanting to hurt yourself or end your life
 - Withdrawing from friends and family
 - Becoming depressed or having your depression get worse
 - Becoming preoccupied with death and dying
 - Giving away prized possessions

We again urge patients and families to contact their doctor before stopping an epilepsy medication because this may possibly lead to seizures and worsening of mood.