

Medication Guide
ZONISADE™ (Zaan-i-said)
(zonisamide oral suspension)

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

- **ZONISADE may cause serious skin reactions that can cause death.** These serious skin reactions may include a severe rash with blisters and peeling skin, especially around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome). ZONISADE may also cause a rash with blisters and peeling skin over much of the body (toxic epidermal necrolysis). Call your healthcare provider right away if you develop a skin rash.
- **ZONISADE can cause blood cell changes such as reduced red and white blood cell counts.** Call your healthcare provider right away if you develop fever, sore throat, sores in your mouth, or easy bruising.
- **ZONISADE can cause other types of allergic reactions or serious problems that may affect different parts of the body such as your liver, kidneys, heart, or blood cells.** You may or may not have a rash with these types of reactions. These reactions can be very serious and can cause death. Call your healthcare provider right away if you have:
 - fever
 - rash
 - swelling of your face
 - weakness, fatigue
 - severe muscle pain
 - swollen lymph glands
 - unusual bruising or bleeding
 - yellowing of your skin or the white part of your eyes
- **ZONISADE may cause decreased sweating and increased body temperature (fever).** People, especially children, should be watched for signs of decreased sweating and fever, especially in hot temperatures. Some people may need to be hospitalized for this condition. If you have decreased sweating with or without a fever, call your healthcare provider right away.
- **ZONISADE may cause eye problems.** Serious eye problems include:
 - any sudden decrease in vision with or without eye pain and redness
 - a blockage of fluid in the eye causing increased pressure in the eye (secondary angle closure glaucoma)

These eye problems can lead to permanent loss of vision if not treated.

Call your healthcare provider right away if you have any new eye symptoms, including any new problems with your vision.

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

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.

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

- Stopping ZONISADE suddenly can cause serious problems.
- Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).
- **ZONISADE can increase the level of acid in your blood (metabolic acidosis).** If left untreated, metabolic acidosis can cause brittle or soft bones (osteoporosis, osteomalacia, osteopenia), kidney stones and can slow the rate of growth in children. Metabolic acidosis can happen with or without symptoms. Call your healthcare provider right away if you have any of these symptoms:

- fast breathing
- feel tired
- feel changes in heartbeat
- not feel hungry (loss of appetite)
- have trouble thinking clearly

Your healthcare provider should do a blood test to measure the level of acid in your blood before and during your treatment with ZONISADE.

- **ZONISADE may cause problems with thinking and alertness.** ZONISADE may affect how you think and cause confusion, problems with concentration, attention, memory, or speech. ZONISADE may cause depression or psychotic symptoms (such as seeing or hearing things that are really not there), tiredness, and sleepiness.

ZONISADE can have other serious side effects. For more information ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you. Be sure to read the section "**What are the possible side effects of ZONISADE?**".

What is ZONISADE?

- ZONISADE is a prescription medicine that is used with other medicines to treat partial seizures in adults and children 16 years of age and older.
- It is not known if ZONISADE is safe and effective in children under 16 years of age.

Do not take ZONISADE if you:

- are allergic to sulfonamides or zonisamide.

Before taking ZONISADE, 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.
- have a history of metabolic acidosis (too much acid in your blood).
- have weak, brittle bones or soft bones (osteomalacia, rickets, osteopenia, or osteoporosis).
- have a growth problem.
- are on a diet high in fat called a ketogenic diet.
- have diarrhea.
- have high blood levels of ammonia.
- are pregnant or plan to become pregnant. ZONISADE may harm your unborn baby. Women who can become pregnant should use effective birth control. Tell your healthcare provider right away if you become pregnant or think you may be pregnant while taking ZONISADE. You and your healthcare provider should decide if you should take ZONISADE while you are pregnant.

There is pregnancy registry for women who are exposed to ZONISADE during pregnancy. If you become pregnant while taking ZONISADE, 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 or plan to breastfeed. ZONISADE can pass into your breast milk. It is not known if ZONISADE in your breast milk can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take ZONISADE. If you breastfeed while taking ZONISADE, check your baby and call your healthcare provider right away if your baby has increased sleepiness, decreased hunger, or elevated body temperature.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take ZONISADE?

- Take ZONISADE exactly as your healthcare provider tells you to take it.
- ZONISADE is for oral use only.
- Your healthcare prescriber may change your dose. **Do not** change your dose without talking to your healthcare provider.
- Your pharmacist will provide a measuring device and instructions for measuring the correct dose. Do not use a household teaspoon.
- Take ZONISADE 1 or 2 times each day, with or without food.
- Shake ZONISADE well each time before taking.
- If you take too much ZONISADE, call your local Poison Control Center or go to the nearest emergency

room right away.

- **Do not** stop taking ZONISADE without talking to your healthcare provider. Stopping ZONISADE suddenly can cause serious problems. If you have epilepsy and you stop taking ZONISADE suddenly, you may have an increase in seizures, including seizures that will not stop (status epilepticus).

What should I avoid while taking ZONISADE?

- You should not drink alcohol or take other drugs that make you sleepy or dizzy while taking ZONISADE until you talk to your health care provider. ZONISADE taken with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
- Do not drive a car or operate machinery until you know how ZONISADE affects you. ZONISADE can slow your thinking and motor skills.

What are the possible side effects of ZONISADE?

ZONISADE can cause serious side effects including:

See "**What is the most important information I should know about ZONISADE?**"

- **high blood ammonia levels.** High ammonia in the blood can affect your mental status, slow your alertness, make you feel tired, or cause vomiting. Call your healthcare provider right away if you develop unexplained tiredness, vomiting, slow alertness or changes in your mental status.
- **kidney stones.** Drink plenty of fluids while you take ZONISADE to decrease your chances of getting kidney stones. Call your healthcare provider right away if you get back pain, stomach pain, or blood in your urine.
- **decrease in kidney function.** ZONISADE may cause a decrease in kidney function. Your healthcare provider should do a blood test to measure your kidney function before and during treatment with ZONISADE.

The most common side effects of ZONISADE include:

- drowsiness
- dizziness
- agitation or irritability
- loss of appetite
- trouble with walking and coordination
- difficulty with memory or concentration

These are not all of the possible side effects of ZONISADE. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Azurity Pharmaceuticals, Inc. at 1-855-379-0383.

How should I store ZONISADE?

- Store ZONISADE at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect ZONISADE from light.
- Throw away (discard) any unused ZONISADE 30 days after first opening the bottle.

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

General Information about the safe and effective use of ZONISADE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZONISADE for a condition for which it was not prescribed. Do not give ZONISADE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ZONISADE that is written for health professionals.

What are the ingredients in ZONISADE?

Active ingredient: zonisamide

Inactive ingredients: carboxymethylcellulose sodium, citric acid monohydrate, microcrystalline cellulose, purified water, sodium benzoate, strawberry flavor, sucralose, trisodium citrate dihydrate, and xanthan gum.

Manufactured for:

Azurity Pharmaceuticals, Inc.

Wilmington, MA 01887 USA