

Of the 20+ FDA-approved oral formulations of zonisamide, **ZONISADE®** is the **ONLY** alternative formulation to capsules.<sup>1</sup>

# **Important Safety Information**

# ZONISADE® (zonisamide oral suspension), 100 mg/5 mL

ZONISADE is indicated as adjunctive therapy for the treatment of partial-onset seizures in adults and pediatric patients 16 years of age and older.

A calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device. Ask your pharmacist or doctor for assistance in the selection of a measuring device.



# With ZONISADE®, there is no need to:



mix or crush



cut or split



compound



### **Strawberry flavor**

A sweet taste in an oral liquid solution



## **Ready-to-use**

Just carefully measure your dose and drink

Remember to throw away any unused **ZONISADE**® 30 days after opening



## Widely available

You can find **ZONISADE®** at most pharmacies within 24 hours



### Flexible dosing

So you can get the right dose your doctor prescribes, every time

# Successful treatment depends on good communication

As a patient, parent, or caregiver, you play an important role in treatment decisions. So talk to your doctor to find out if **ZONISADE**® is right for you or your loved one, and ask your pharmacist if you have questions about **ZONISADE**® and how to take it.

#### **Additional Important Safety Information**

Do not take ZONISADE if you are allergic to medicines that contain sulfa, zonisamide, or any formulation ingredients.

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

ZONISADE may cause serious side effects, including:

- Serious skin rash that can cause death
- Serious allergic reactions that may affect different parts of the body
- Less sweating and increase in your body temperature (fever)
- Serious eye problems
- Suicidal thoughts or actions in some people
- Increased level of acid in your blood (metabolic acidosis)
- Problems with your concentration, attention, memory, mood, thinking, speech, or language
- Blood cell changes such as reduced red and white blood cell counts

- Back pain, stomach pain, or blood in your urine may indicate you have a kidney stone.
- Drink plenty of fluids when taking ZONISADE to decrease your chances of getting kidney stones
- New or worse depression, sudden changes in mood or behavior, loss of contact with reality (sometimes associated with hearing voices or seeing things that are not really there), feeling sleepy or tired, trouble concentrating, and speech or language problems. Call your healthcare provider right away if you have any problems with the symptoms listed above
- High ammonia levels in the blood can affect your mental activities, slow your alertness, make you feel tired, or cause vomiting





Zonisamide has been known and trusted by doctors for over 22 years. It was first approved in the United States in 2000 as adjunctive therapy in the treatment of partial-onset seizures in adults with epilepsy<sup>2</sup>

The beyond-use date for ZONISADE® is 30 days after a bottle is first opened.

# Prescription coverage doesn't have to be difficult



# If eligible,\* you may be able to receive ZONISADE® for as little as \$0 co-pay

- Automatic co-pay at local pharmacies no calls, cards, or coupons necessary
- Instant co-pay savings at 70,000+ pharmacies





For answers to your questions about **ZONISADE**® coverage, visit azuritysolutions.com.



\*View Eligibility Restrictions, Terms, and Conditions at azuritysolutions.com.

# **Additional Important Safety Information (cont.)**

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

- have or have had depression, mood problems, suicidal thoughts
   have weak, brittle bones or soft bones (osteomalacia, or behavior
- have kidney problems
- have liver problems
- have a history of too much acid in your blood (metabolic acidosis)
- 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

#### What should I avoid while taking ZONISADE?

- Do not drink alcohol or take other drugs that make you sleepy or dizzy while taking ZONISADE until you talk to your healthcare provider. ZONISADE taken with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness
- Do not drive, operate heavy machinery, or do other dangerous activities until you know how ZONISADE affects you. ZONISADE can slow your thinking and motor skills

## **Additional Important Safety Information (cont.)**

#### Certain reactions can be very serious and can cause death.

Watch for decreased sweating and fever, especially when it is hot and especially in children taking ZONISADE.

#### While taking ZONISADE, call your healthcare provider right away if you have:

- High fever, recurring fever, long-lasting fever, or less sweat than normal
- · severe muscle pain
- rash
- swollen lymph glands

- · swelling of your face
- unusual bruising or bleeding
- weakness or fatigue
- · yellowing of your skin or the white part of your eyes

#### Also, call your healthcare provider right away if you:

- · have any new eye symptoms, including any eye pain or redness or any new problems with your vision
- have sudden changes in mood or behavior, loss of contact with reality (sometimes associated with hearing voices or seeing things that are not really there), feel sleepy or tired, have trouble concentrating, or speech and language problems
- develop a fever, sore throat, sores in your mouth, or unusual bruising

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

# Like other antiepileptic drugs, ZONISADE may cause suicidal thoughts or actions. 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
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- · Panic attacks
- An extreme increase in activity and talking (mania)
- Feeling agitated or restless
- Trouble sleeping (insomnia)
- · New or worse irritability
- · Acting aggressive or being angry or violent
- Acting on dangerous impulses
- Other unusual changes in behavior or mood

#### 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).

#### Tell your healthcare provider if you:

- 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 while taking ZONISADE. You and your
  healthcare provider Oshould decide if you should take ZONISADE while you are pregnant. 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

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

#### The most common side effects of ZONISADE include:

- drowsiness
- · loss of appetite
- dizziness
- difficulty with memory or

- concentration
- trouble with walking and coordination
- · agitation or irritability

Store ZONISADE at room temperature and discard unused portions 30 days after first opening.

The Important Safety Information does not include all the information needed to use ZONISADE safely and effectively. Please talk to your healthcare provider and see the complete Prescribing Information for <u>ZONISADE</u>.

To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or <a href="https://www.fda.gov/MedWatch">www.fda.gov/MedWatch</a>.

PP-ZON-US-0061

#### Please see full <u>Prescribing Information</u> at <u>ZONISADE.com</u>.

#### Reference:

- Orange Book: approved drug products with therapeutic equivalence evaluations. Accessed October 26, 2023. <a href="https://www.accessdata.fda.gov/scripts/cder/ob/search\_product.cfm">https://www.accessdata.fda.gov/scripts/cder/ob/search\_product.cfm</a>
- 2. ZONISADE [package insert]. Woburn, MA: Azurity Pharmaceuticals.; 2023



