

**Zonisamide Cas No. : 68291-97-4**

This medication is used with other medications to control certain types of seizure problems (e.g., partial seizures). This medication is usually used when other medications have not been effective in controlling your seizures. Controlling seizures helps to prevent injury from falling and allows you to lead a more normal life. Zonisamide belongs to a class of drugs known as anticonvulsants. It works by controlling the abnormal electrical activity in the brain that occurs during a seizure.

Active Pharmaceuticals Ingredients Manufacturers

**Taj Pharmaceuticals Ltd.****Zonisamide****CAS No. : 68291-97-4****Synonyms: (IUPAC) name**

1,2-benzisoxazole-3-methanesulfonamide

**Identifiers**

CAS number 68291-97-4

ATC code N03AX15

PubChem 5734

DrugBank APRD00004

**Chemical data**Formula C<sub>8</sub>H<sub>8</sub>N<sub>2</sub>O<sub>3</sub>S

Mol. mass 212.227 g/mol

Physical data

Melt. point 162 °C (324 °F)

**Pharmacokinetic data**

Bioavailability

Protein binding 40%

Metabolism Hepatic

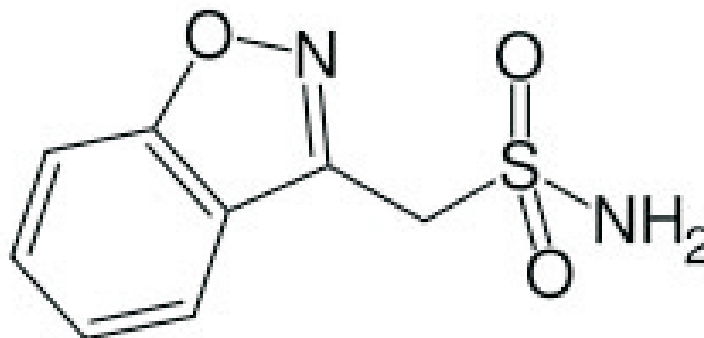
Half life 105 hours in red blood cells, 63 hours in plasma

Excretion Renal

Therapeutic considerations

Prescription only

Routes Oral



Zonisamide is an antiseizure drug chemically classified as a sulfonamide and unrelated to other antiseizure agents. The active ingredient is zonisamide, 1,2-benzisoxazole-3-methanesulfonamide.

The empirical formula is C<sub>8</sub>H<sub>8</sub>N<sub>2</sub>O<sub>3</sub>S with a molecular weight of 212.23. Zonisamide is a white powder, pK<sub>a</sub> = 10.2, and is moderately soluble in water (0.80 mg/mL) and 0.1 N HCl (0.50 mg/mL).

**USES**

This medication is used with other medications to control certain types of seizure problems (e.g., partial seizures). This medication is usually used when other medications have not been effective in controlling your seizures. Controlling seizures helps to prevent injury from falling and allows you to lead a more normal life.

Zonisamide belongs to a class of drugs known as anticonvulsants. It works by controlling the abnormal electrical activity in the brain that occurs during a seizure.

**HOW TO USE**

Take this medication by mouth with or without food, usually 1-2 times daily or as directed by your doctor. Take with food or milk if stomach upset occurs.



**Taj Pharmaceuticals Ltd.**  
**Z o n i s a m i d e**

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Your doctor will start you on a smaller dose once daily, increasing it every 2 weeks until you are taking the full dose. Swallow the capsules whole. Do not crush or chew the capsules.

Dosage is based on your age, medical condition, blood levels of zonisamide, and response to therapy. It may take several weeks to months until your doctor determines the correct dose for controlling your seizures.

This medication works best when the amount of drug in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals. To help you remember, take it at the same time each day.

### **SIDE EFFECTS**

Dizziness, drowsiness, trouble sleeping, tiredness, headache, staggering walk/clumsiness, nausea, vomiting, gas, loss of appetite, mental/mood changes (e.g., difficulty concentrating, slowed thinking, memory loss), stomach/abdominal pain, weight loss, diarrhea, double vision, difficulty speaking, or constipation may occur.

This medication rarely may cause mood or behavior changes, such as anxiety, agitation, hostility, pressured/rapid speech, or thoughts of suicide. Tell your doctor immediately if you develop unusual (possibly sudden) mood changes. This medication may rarely cause a serious immune system problem (systemic lupus erythematosus).

Tell your doctor immediately if you experience any of these unlikely but serious side effects: unusual tiredness, joint/muscle aches, unusual fever, butterfly-shaped facial rash, swollen glands, bloody/pink urine, swelling of the feet/ankles (edema).

### **PRECAUTIONS**

Before taking zonisamide, tell your doctor or pharmacist if you are allergic to it; or to other sulfa-type drugs; or if you have any other allergies.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver problems, kidney problems, severe lung disease, anemia, low white blood cell counts, mental/mood problems

This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such using machinery. Avoid alcoholic beverages. Driving is usually not allowed by law if you have new or recent seizures.

This medication can cause decreased sweating, which can lead to a serious, possibly fatal increase in body temperature (heatstroke). Avoid becoming overheated in hot weather, saunas, and during exercise and other strenuous activities. Caution is advised when using this drug in children because they may be more sensitive to the effects of this drug, especially drowsiness, dizziness, and heatstroke.

### **MISSED DOSE**

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

### **STORAGE**

Store at room temperature at about 77 degrees F (25 degrees C) away from light and moisture. Brief storage at 59-86 degrees F (15-30 degrees C) is permitted. Protect from heat. Discard any melted or partially full capsules. Keep all medicines away from children



## DOSAGE

Zonisamide are recommended as adjunctive therapy for the treatment of partial seizures in adults. Safety and efficacy in pediatric patients below the age of 16 have not been established. Zonisamide should be administered once or twice daily, using 25 mg, 50 mg or 100 mg . Zonisamide are given orally and can be taken with or without food. should be swallowed whole.

### Adults over Age 16:

The prescriber should be aware that, because of the long half-life of Zonisamide, up to two weeks may be required to achieve steady state levels upon reaching a stable dose or following dosage adjustment. Although the regimen described below is one that has been shown to be tolerated, the prescriber may wish to prolong the duration of treatment at the lower doses in order to fully assess the effects of Zonisamide at steady state, noting that many of the side effects of Zonisamide are more frequent at doses of 300 mg per day and above. Although there is some evidence of greater response at doses above 100-200 mg/day, the increase appears small and formal dose-response studies have not been conducted.

### Patients with Renal or Hepatic Disease:

Because Zonisamide is metabolized in the liver and excreted by the kidneys, patients with renal or hepatic disease should be treated with caution, and might require slower titration and more frequent monitoring.

**Note /Government Notification:** These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:  
91 022 30601000.

This leaflet was prepared by  
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