

- the starting dose is 50 mg daily taken in two equal doses of 25 mg
- this may be increased by up to 100 mg at intervals of one to two weeks
- the recommended daily dose is between 300 mg and 500 mg

- some people respond to lower doses. The dose may be increased more slowly if you experience side effects, are elderly or if you suffer from kidney or liver problems.

Use in children (aged 6 to 11 years) and adolescents (aged 12 to 17 years) weighing at least 20 kg:

- the starting dose is 1 mg per kg of body weight taken once a day
- this may be increased by 1 mg per kg of body weight at intervals of one to two weeks
- the recommended daily dose is 6 to 8 mg per kg for a child with a body weight of up to 55 kg or 300 to 500 mg for a child with a body weight more than 55 kg (which ever dose is lower) taken once a day.

Example: A child who weighs 25 kg should take 25 mg once a day for the first week, and then increase the daily dose by 25 mg at the start of each week until a daily dose between 150 to 200 mg is reached.

If you feel that the effect of Zonisamide Teva is too strong or too weak, talk to your doctor or pharmacist.

- Zonisamide Teva capsules must be swallowed whole with water
- do not chew the capsules
- Zonisamide Teva can be taken once or twice daily, as instructed by your doctor
- if you take Zonisamide Teva twice a day, take half the daily dose in the morning and half in the evening.

If you take more Zonisamide Teva than you should

If you may have taken more Zonisamide Teva than you should, tell a carer (relative or friend), your doctor or pharmacist **immediately**, or contact your nearest hospital casualty department, taking your medicine with you. You may become sleepy and could lose consciousness. You might also feel sick, have a sore stomach, muscle twitches, eye movement, feel faint, have a slowed heart beat, and reduced breathing and kidney function. Do not try to drive.

If you forget to take Zonisamide Teva

- if you forget to take a dose, don't worry: take the next dose when it is due
- do not take double the dose to make up for the forgotten dose.

If you stop taking Zonisamide Teva

- Zonisamide Teva is meant to be taken as a long-term medicine. Do not reduce your dose or stop your medicine unless your doctor tells you to
- if your doctor advises you to stop taking Zonisamide Teva your dose will be reduced gradually to lower the risk of more seizures.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Zonisamide Teva belongs to a group of medicines (sulphonamides) that can cause severe allergic reactions, severe skin rashes, and blood disorders, which very rarely can be fatal.

Contact your doctor immediately if you:

- have difficulty breathing, a swollen face, lips or tongue, or a severe skin rash as these symptoms may indicate that you are having a **severe allergic reaction**
- have signs of **overheating** - high body temperature but little or no sweating, rapid heartbeat and breathing, muscle cramps, and confusion
- have **thoughts of harming or killing yourself**. A small number of people being treated with anti-epileptics such as Zonisamide Teva have had thoughts of harming or killing themselves
- have **pain in your muscles** or a feeling of weakness, as this may be a sign of abnormal muscle breakdown which can lead to kidney problems
- get a sudden **pain in your back or stomach**, have pain on urinating (passing water) or notice blood in your urine, as this may be a sign of kidney stones.
- develop visual problems such as eye pain or blurred vision while taking Zonisamide Teva

Contact your doctor as soon as possible if you:

- have an unexplained skin rash, as this could develop into a more severe skin rash or skin peeling
- feel unusually tired or feverish, have a sore throat, swollen glands, or find that you bruise more easily, as this may mean you have a blood disorder
- have signs of increased acid level in the blood - headaches, drowsiness, shortness of breath and loss of appetite. Your doctor may need to monitor or treat this.

Your doctor may decide that you should stop using Zonisamide Teva.

The most common side effects of Zonisamide Teva are mild. They occur during the first month of treatment and usually decrease with continued treatment. In children ages 6 - 17 years old, side effects were consistent with those described below with the following exceptions: pneumonia, dehydration, sweating decreased (common) and abnormal liver enzymes (uncommon).

Very common side effects: may affect more than 1 in 10 people

- agitation, irritability, confusion, depression
- poor muscle coordination, dizziness, poor memory, sleepiness, double vision
- loss of appetite, decreased blood levels of bicarbonate (a substance that prevents your blood from becoming acidic).

Common side effects: may affect up to 1 in 10 people

- difficulty sleeping, strange or unusual thoughts, feeling anxious or emotional
- slowed thoughts, loss of concentration, speech abnormalities, abnormal skin sensation (pins and needles), tremor, involuntary movement of the eyes
- kidney stones
- skin rashes, itching, allergic reactions, fever, tiredness, flu-like symptoms, hair loss
- ecchymosis (a small bruise caused by blood leaking from broken blood vessels in the skin)

- loss of weight, nausea, indigestion, stomach pains, diarrhoea (loose stools), constipation
- swelling of the feet and legs.

Uncommon side effects: may affect up to 1 in 100 people

- anger, aggression, thoughts of suicide, suicide attempt
- vomiting
- gall bladder inflammation, gallstones
- urinary stones
- lung infection/inflammation, urinary tract infections
- low blood potassium levels, convulsions/seizures.

Very rare side effects: may affect up to 1 in 10,000 people

- hallucinations, memory loss, coma, neuroleptic malignant syndrome (inability to move, sweating, fever, incontinence), status epilepticus (prolonged or repeated seizures)
- breathing disorders, shortness of breath, inflammation of the lungs
- inflammations of the pancreas (severe pain in the stomach or back)
- liver problems, kidney failure, increased blood levels of creatinine (a waste product that your kidneys should normally remove)
- severe rashes or skin peeling (at the same time you may feel unwell or develop a fever)
- abnormal muscle breakdown (you may feel pain or weakness in your muscles) which can lead to kidney problems
- swollen glands, blood disorders (reduction in the number of blood cells, which can make infection more likely and can make you look pale, feel tired and feverish, and bruise more easily)
- decreased sweating, overheating.
- glaucoma, which is a blockage of fluid in the eye causing increased pressure in the eye. Eye pain, blurred vision or decreased vision may occur and can be signs of glaucoma.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Zonisamide Teva

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice any damage to the capsules, blister or carton or any visible signs of deterioration in the medicine. Return the pack to your pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Zonisamide Teva contains

- The active substance is zonisamide. Zonisamide Teva 25 mg Capsules, Hard contain 25 mg of zonisamide. Zonisamide Teva 50 mg Capsules, Hard contain 50 mg of zonisamide. Zonisamide Teva 100 mg Capsules, Hard contain 100 mg of zonisamide.
- The other ingredients that are present in the capsule contents are: cellulose, microcrystalline, sodium lauryl sulfate, silica, colloidal hydrated and hydrogenated vegetable oil type I.
- The capsule shell contains: titanium dioxide (E171), gelatin, additionally the 50 mg capsule shell contains black iron oxide (E172) and 100 mg capsule shell contains red iron oxide (E172).
- The imprinting ink contains shellac, propylene glycol, strong ammonia solution, black iron oxide (E172) and potassium hydroxide.

What Zonisamide Teva looks like and contents of the pack

- Zonisamide Teva 25 mg hard gelatin size 4 capsules, approx. 14 mm x 5 mm, with white cap and white body, filled with white to off white granulate, printed with "25" on the body.
- Zonisamide Teva 50 mg hard gelatin size 3 capsules, approx. 16 mm x 6 mm, with grey cap and white body, filled with white to off white granulate, printed with "50" on the body.
- Zonisamide Teva 100 mg hard gelatin size 1 capsules, approx. 19 mm x 7 mm, with orange cap and white body, filled with white to off white granulate, printed with "100" on the body.

Zonisamide Teva 25 mg Capsules, Hard are packed in blisters of 7, 14, 28, 30, 56, 60 or 100 capsules, hard.

Zonisamide Teva 50 mg Capsules, Hard are packed in blisters of 7, 14, 28, 30, 56, 60 or 100 capsules, hard.

Zonisamide Teva 100 mg Capsules, Hard are packed in blisters of 7, 14, 28, 30, 56, 60, 98, 100 or 196 (98 x 2 - multipack) capsules, hard.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Manufacturer

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