

Zonisamide Waymade 25 mg hard capsules Zonisamide Waymade 50 mg hard capsules Zonisamide Waymade 100 mg hard capsules

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zonisamide Waymade is and what it is used for
2. What you need to know before you take Zonisamide Waymade
3. How to take Zonisamide Waymade
4. Possible side effects
5. How to store Zonisamide Waymade
6. Contents of the pack and other information

1. What Zonisamide Waymade is and what it is used for

The name of your medicine is Zonisamide Waymade 25 mg, 50 mg and 100 mg hard capsules (referred to as Zonisamide Waymade in this leaflet).

Zonisamide Waymade contains the active substance zonisamide, and is used as an antiepileptic medicine.

Zonisamide Waymade is used to treat seizures that affect one part of the brain (partial seizure), which may or may not be followed by a seizure affecting all of the brain (secondary generalisation).

Zonisamide Waymade may be used:

- On its own to treat seizures in adults
- With other antiepileptic medicines to treat seizures in adults, adolescents, and children aged 6 years and above.

2. What you need to know before you take Zonisamide Waymade

Do not take Zonisamide Waymade:

If you:

- are allergic to zonisamide or any of the other ingredients in this medicine (listed in section 6),
- are allergic to other sulphonamide medicines. Examples include: sulphonamide antibiotics, thiazide diuretics, and sulfonyleurea antidiabetes medicines.
- are allergic to peanut or soya, do not use this medicinal product.

Warnings and precautions

Zonisamide Waymade belongs to a group of medicines (sulphonamides) which can cause severe allergic reactions, severe skin rashes, and blood disorders, which very rarely can be fatal (see section 4. 'Possible side effects').

Serious rashes occur in association with Zonisamide therapy, including cases of Stevens-Johnson syndrome.

The use of Zonisamide Waymade may lead to high levels of ammonia in the blood which could lead to a change in brain function, especially if you are also taking other medicines which can increase ammonia levels (for example valproate), have a genetic disorder causing build-up of too much ammonia in the body (urea cycle disorder), or if you have liver problems. Tell your doctor immediately if you become unusually drowsy or confused.

Talk to your doctor or pharmacist before taking Zonisamide Waymade:

- if you are younger than 12 years old, as you may be at greater risk of *decreased sweating, heat stroke, pneumonia and liver problems*. If you are younger than 6 years old, Zonisamide Waymade is not recommended for you.
- if you are elderly, as your dose of zonisamide may need adjusting, and you may be more likely to develop an allergic reaction, severe skin rash, swelling of the feet and legs, and itchiness when taking Zonisamide Waymade (see section 4 'Possible side effects').
- if you suffer from liver problems, as your dose of zonisamide may need adjusting.
- if you have eye problems such as glaucoma.
- if you suffer from kidney problems as your dose of zonisamide may need adjusting.
- if you have previously suffered from kidney stones, as you may be at increased risk of developing more kidney stones.

Reduce the risk of kidney stones by drinking sufficient water.

- if you live in a place or are on holiday in a place where the weather is warm. Zonisamide Waymade can make you perspire less, which can cause your body temperature to increase.

Reduce the risk of overheating by drinking sufficient water and keeping cool.

- if you are underweight, or have lost a lot of weight as Zonisamide Waymade can cause you to lose more weight. Tell your doctor as this may need to be monitored.
- If you are pregnant or could become pregnant (see section 'Pregnancy, breast-feeding and fertility' for further information).

If any of these applies to you, tell your doctor before you take Zonisamide Waymade.

Children and adolescents

Talk to your doctor about the following risks:

Preventing overheating and dehydration in children

Zonisamide can cause your child to sweat less and overheat and if your child is not treated this can lead to brain damage and death. Children are most at risk especially in hot weather.

When your child is taking Zonisamide Waymade:

- Keep your child cool especially in hot weather
- Your child must avoid heavy exercise especially when the weather is hot
- Give your child plenty of cold water to drink
- Your child must not take these medicines: carbonic anhydrase inhibitors (like topiramate and acetazolamide), and anticholinergic agents (like clomipramine, hydroxyzine, diphenhydramine, haloperidol, imipramine and oxybutynin).

If your child's skin feels very hot with little or no sweating, becomes confused, has muscle cramps, or your child's heartbeat or breathing becomes rapid:

- Take your child to a cool, shaded place
- Sponge your child's skin with cool (not cold) water
- Give your child cold water to drink
- Seek urgent medical assistance

- Body weight: **You should monitor your child's weight every month and see your doctor as soon as possible if your child is not gaining enough weight.** Zonisamide Waymade is not recommended for children who are underweight or have a small appetite, and should be used with caution in those below 20 kg

- Increased acid level in the blood and kidney stones: Reduce these risks by ensuring that your child drinks enough water and is not taking any other medicine which could cause kidney stones (see section 'Other medicines and Zonisamide Waymade'). Your doctor will monitor your child's blood bicarbonate levels and kidneys (see also section 4).

Do not give this medicine to children below the age of 6 years because it is not known for this age group whether the potential benefits are greater than the risks.

Other medicines and Zonisamide Waymade

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

- Zonisamide Waymade should be used carefully in adults when taken with medicines that can cause kidney stones, like topiramate or acetazolamide. In children, this combination is not recommended.
- Zonisamide Waymade could possibly increase your blood levels of medicines like digoxin and quinidine, and so a reduction in their dose may be required.
- Other medicines like phenytoin, carbamazepine, phenobarbitone and rifampicin can decrease your blood levels of zonisamide, which may require an adjustment of your dose of Zonisamide Waymade.

Zonisamide Waymade with food and drink

Zonisamide Waymade can be taken with or without food.

Pregnancy, breast-feeding and fertility

- If you are pregnant, or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby.
- If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before you become pregnant.
- You should not stop your treatment without discussing this with your doctor. Suddenly stopping may lead to breakthrough seizures which may harm you and your unborn baby. It is important that your epilepsy remains well controlled.

Pregnancy

You must only take Zonisamide Waymade during your pregnancy if your doctor tells you to.

If you are a woman of childbearing age you must use adequate contraception while taking and for one month after stopping Zonisamide Waymade.

Pharma
code

Studies have shown an increased risk of physical birth abnormalities in children of women taking epilepsy medicines during pregnancy. The risk of physical birth abnormalities may increase when more than one epilepsy medicine is used at the same time. Where possible, your doctor should consider using one epilepsy medicine to control your epilepsy.

More research is needed to better understand whether taking zonisamide during pregnancy increases the risk of having a baby born with a physical birth abnormality or a learning or thinking disability.

Studies have shown that babies born to mothers using zonisamide during pregnancy were smaller than expected for their age at birth, compared with babies born to mothers treated with lamotrigine monotherapy.

Make sure you are fully informed about the risks and benefits of using zonisamide for epilepsy during pregnancy.

Do not breast-feed whilst taking, or for one month after stopping Zonisamide Waymade.

There are no clinical data available on the effects of zonisamide on human fertility. Studies in animals have shown changes in fertility parameters.

Driving and using machines

Zonisamide Waymade may affect your concentration, ability to react/respond, and may make you feel sleepy, particularly at the beginning of your treatment or after your dose is increased. Be especially careful while driving or operating machinery, if Zonisamide Waymade affects you in this way.

Important information about some of the ingredients of Zonisamide Waymade

Zonisamide Waymade contains Sunset yellow (E110), Allura red (E129) and hydrogenated vegetable oil (from soybean)

Zonisamide Waymade 100 mg hard capsules contain a yellow colour called Sunset yellow (E110) and a red colour called Allura red (E129), which may cause allergic reactions.

Zonisamide Waymade contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Zonisamide Waymade

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended adult dose

When you take Zonisamide Waymade on its own

- The starting dose is 100 mg taken once a day.
- This may be increased by up to 100 mg at intervals of two weeks.
- The recommended dose is 300 mg once a day.

When you take Zonisamide Waymade with other antiepileptic medicines

- 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 (whichever 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 Waymade is too strong or too weak, talk to your doctor or pharmacist.

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

If you take more Zonisamide Waymade than you should

If you may have taken more Zonisamide Waymade than you should (or if somebody else has taken some of your medicine), 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 Waymade

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

If you stop taking Zonisamide Waymade

Zonisamide Waymade 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 Waymade, your dose will be reduced gradually to lower the risk of more seizures.

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

4. Possible side effects

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

Zonisamide Waymade 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.

Serious side effects

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.
- you have signs of overheating - high body temperature but little or no sweating, rapid heartbeat and breathing, muscle cramps, and confusion.
- you have thoughts of harming or killing yourself. A small number of people being treated with antiepileptics such as Zonisamide Waymade have had thoughts of harming or killing themselves.
- you 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.
- you 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.
- you develop visual problems such as eye pain or blurred vision while taking Zonisamide Waymade.

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.
- you 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.
- you 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 Waymade

The most common side effects of Zonisamide Waymade 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, pharmacist or nurse. 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 Waymade

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 the carton after EXP. The expiry date refers to the last day of that month. Do not store above 30°C.

Do not use 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 require. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zonisamide Waymade contain

The active substance in Zonisamide Waymade is zonisamide.

Zonisamide Waymade 25 mg hard capsules

contain 25 mg zonisamide.

Zonisamide Waymade 50 mg hard capsules

contain 50 mg zonisamide.

Zonisamide Waymade 100 mg hard capsules

contain 100 mg zonisamide.

The other ingredients present in the capsule contents are: microcrystalline cellulose, hydrogenated vegetable oil (from soybean), sodium laurilsulfate and silica colloidal anhydrous.

The capsule shell contains: gelatin, titanium dioxide (E171), shellac, propylene glycol and black printing ink (contains: black iron oxide (E172), shellac, propylene glycol, strong ammonia solution (pH adjustment) and potassium hydroxide (pH adjustment)).

Additionally the 100 mg capsule shell contains Sunset yellow (E110) and Allura red (E129).

See Section 2 for important information about the ingredients: Sunset yellow (E110), Allura red (E129) and hydrogenated vegetable oil (from soybean).

What Zonisamide Waymade looks like and contents of the pack

Zonisamide Waymade 25 mg hard capsules have a size "4" white opaque body and a white opaque cap and are imprinted with "1" on the cap and "22" on the body in black ink.

Zonisamide Waymade 50 mg hard capsules have a size "3" white opaque body and a grey opaque cap and are imprinted with "1" on the cap and "21" on the body in black ink.

Zonisamide Waymade 100 mg hard capsules have a size "1" white opaque body and a red opaque cap and are imprinted with "1" on the cap and "20" on the body in black ink.

Zonisamide Waymade is packaged in blister packs supplied in cartons containing:

25 mg:	14 capsules
50 mg:	56 capsules
100 mg:	56 capsules

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR, UK

Manufacturer

Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR, UK

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