### ZONISAMIDE TEVA 25 mg, 50 mg AND 100 mg CAPSULES, HARD

## (AGE LEAFLET TION FOR THE

Read all of this leaflet carefully before you start taking this medicine because it contains

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 pharmacist. - This modicine 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 house

If you get any side effects, talk to your docto

or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4. WHAT IS IN THIS LEAFLET:

#### 1. What Zonisamide Teva is and what it is used

for 2. What you need to know before you take Zonisamide Teva 3. How to take Zonisamide Teva

Possible side effects

5. How to store Zonisamide Teva 6. Contents of the pack and other inform

## What Zonisamide Teva is and what it is used for

Zonisamide Teva contains the active substanc zonisamide, and is used as an anti-epileptic medicine

Zonisamide Teva 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 Teva may be used: on its own to treat seizures in adults
- on its own to treat seizures in adults with other anti-epileptic medicines to treat seizures in adults, adolescents, and children aged 6 years and above.

## 2 What you need to know before you take Zonisamide Teva

- Do not take Zonisamide Teva: if you are allergic to zonisamide or any of the other ingredients of this medicine (list in section 6)
- if you are allergic to other sulphonamide medicines. Examples include: sulphonamide antibiotics, thiazide diuretics, and sulfonylurea antidiabetes medicines.

and suitonyuirea antidiabetes medicines. Warnings and preceutions Zonisamide Teva belongs to a group of medicines (sulphonamides) which can cause severe allergic reactions, severe skin raehes, and blood disorders, which very rarely can be fatal (see section 4. Possible side effects).

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

The use of 2 conisamide Tow 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

- Talk to your doctor or pharmacist before taking Zonisamide Teva if you: are younger than 12 years old, as you may be at greater risk of decreased aweeting, heat stroke, pneumonia and liver problems. If you are younger than 6 years old, Zonisamide Teva is not recommended for you. are elderly, as your does cont Zonisamide Teva may need adjusting, and you may be more likely to develop an allergio reaction, severe skin rash, swelling of the feet and legs, and tichiness when taking Zonisamide Teva (see asction 4. Possible side effects). suffer from kidney problems, as your dose of Zonisamide Teva may need adjusting. have eye problems such as glaucoma. suffer from kidney problems as your dose of Zonisamide Teva may need adjusting. 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 vater. i vien a place or are on holiday in a place where the weather is warm. Zonisamide Teva can make you perspire less, which can cause your body temperature to increases. Reduce the risk of overheating yodrinking sufficient vater and keeping cool.

- cause your body temperature to increase. Reduce the risk of overheating by drinking sufficient water and keeping cool. are underweight, or have lost a lot of weight as Zonisamide Teva can cause you to lose more weight. Tell your doctor as this may need to be monitored. 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 Teva.

Children and adolescents Talk to your doctor about the following risks

Preventing overheating and dehydration in

- Zonisamide Teva can cause your child to sweat less and overheat and if your child is not treated this can lead to **brain damage and deeth**. Children are most at risk especially in hot weather.
- When your child is taking Zonisamide Teva Keep your child cool especially in hot
- weather Your child must avoid heavy exer
- especially when the weather is hot Give your child plenty of cold water to drink Your child must need child must not take these medicines
- 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

- body weight: You should monitor your 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. Conisamide Teva is not recommended for children who are underweight or hava as amall appetite, and should be used with caution in those below 20 kg increased acid level in the blood and kidney stones: Baduce these risks by ensuring that
- 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 "Other medicines and Zonisamide Teva"). 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 Teva

- Other medicines and Zonisamide Teva Toll your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Zonisamide Teva should be used carefully in adults when taken with medicines that can cause kidney stones, like topiramate or acetzzolamide. In children, this combination is not recommended
  - acetazolamide. In children, this combination is not recommended Zonisamida Teva could possibly increase your blood levels of medicines like digoxin and quindline, and so a reduction in their dose may be required other medicines like phenytoin, carbamazepine, phenotbartione and rifampicin can decrease your blood levels of Zonisamide Teva. Which may require an adjustment of your dose of Zonisamide Teva.

Zonisamide Teva with food and drink Zonisamide Teva can be taken with or

Pregnancy, breast-feeding and fertility If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before you become pregnant.

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.

unborn bapy. If you are planning a pregnancy, talk to your doctor before you stop contraception and before you become pregnant about the possibility of switching to other suitable treatments. If you are or think you might be pregnant, tell your doctor straight away. 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.

You routed that and the Zonisamide Teva during You must only take Zonisamide Teva during your pregnancy if your doctor tells you to. If you are a woman of childbearing age you must use adequate contraception while taking Zonisamide Teva and for one month after stopping Zonisamide Teva.

stopping Zonisamide Teva. Studies have shown an increased risk of physical birth abnormalities in children of women taking epilepsy medicines during pregnancy. The risk of birth defects or neurodevelopment] or your child after taking Zonisamide Teva during your pregnancy is unknown. 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 using one epilepsy medicine to control your epilepsy.

epilepsy. More research is needed to better understand whether taking Zonisamide Teva during pregnancy increases the risk of having a baby born with a physical birth abnormality or a learning or thinking disability. Studies have showed that babies born to mothers using Zonisamide Teva during pregnancy were smaller than expected for their age at birth, compared with babies born to mothers treated with lamotrigine monotherapy. Do not heart food while thisting or for area

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

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

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

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

Sodium Sodium This medicine contains less than 1 mmol sodium (23 mg) per capsule, hard, that is to say essentially 'sodium-free'.

### 3 How to take Zonisamide Teva

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

#### The recommended adult dose

- When you take Zonisamide Teva 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 Teva with other

- anti-e ti-epileptic medicines: the starting does is 50 mg daily taken in two equal doese 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 leptic medicines

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

- ight ta once a da
- 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 body weight more than 55 kg (which ever dose is lower) taken once a day.

# 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 pharmaniet

- Zonisamide Teva capsules must be

- Zonisandle leva capsules must be swallowed eva capsules
  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 take more consensor to a solution 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 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. 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 Interus, atthough not everybody gets them. Zonisamide Teva belongs to a group of medicines (subphonamides) that can cause severe allergic reactions, severe skin rashes, and blood disorders, which very rarely can be fatal. effects, although not everybody gets them.

- 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 severe allergic reaction
- 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
- and confusion have thoughts of harming or killing yourself. A small number of people being treated with anti-peipetics 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 nrohlems.
- 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 there the set of the set of ad the set of ad
- 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.

using Zonisamide leva. 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 abormal liver enzymes (uncommon).

- Very common side effects: may affect more than 1 in 10 people aglitation, initability, 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).

- blood from becoming acidio). 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, stor pains, diarrhoea (loose stools), constipat
  swelling of the feet and legs.
- Uncommon side effects: may affect up to 1 in
- anger, aggression, thoughts of suicide suicide attempt
  - miti 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

- status epilepticus (prolonged or repeated seizures) > preathing disorders, shortness of breath, inflammation of the lungs inflammation of the lungs inflammation of the shortness (severe pain in the stomach or back) > liver problems, kidney failure, increased blood levels of creatinine (a vaste product that your kidneys should normally remove) > severe rashes or skin peeling (at the same time you may feel unwell or davelop a faver) ahormal muscle breakdown (you may feel pain or weakness in your muscles) which can lead to kidney problems > wollen glands, blood disorders (reduction in the number of blood cells, which can make infection more likely and can make you look pale, feel tirted and feverish, and bruise more easily) eleves causing increased pressure in the eye. Eye pain, blurred vision or decreased vision may occur and can be signs of glaucoma.
- 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 Yollow Card Scheme at: www.mkra.gov.uk/yelloweard or search for MHRA.Yollow 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.

#### 6 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 P The expiry date refers to the last day of that month. EXP

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 a visible signs of deterioration in the medicine. Return the pack to your pharmacist. or any

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

## 6 Contents of the pack and other information

Vhat 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, neircorystalline, sodium lauryl sulfate, silica, colloidal hydrated and hydrogenated vegetable oil type I.

colloidal hydrated and hydrogenated vogetable 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 oxide (E172) and potassium hydroxide. ck iron

What Zonisamide Teva looks like and contents of the pack - Zonisami

аск imide Teva 25 mg hard gelatin size 4 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 gray 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 orar 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

Marketing Authorisation Holder

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

Manufacturer TEVA Pharmaceutical Works Private Limited Company, Pallagi út 13, 4042 Debrecen, Hur n. Hungary This leaflet was last revised in 04/2023

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