

## Package leaflet: Information for the user

### Zonisamide Rosemont 20mg/ml Oral Suspension

**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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What Zonisamide Rosemont is and what it is used for

Zonisamide Rosemont 20mg/ml Oral Suspension (called Zonisamide in this leaflet) contains the active substance zonisamide, and is used as an antiepileptic medicine.

Zonisamide 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 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 Rosemont

##### Do not take Zonisamide:

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

#### Warnings and precautions

Zonisamide 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 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 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 is not recommended for 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 (see section 4 Possible side effects).
- suffer from liver problems, as your dose of Zonisamide may need adjusting.
- have eye problems such as glaucoma.
- suffer from kidney problems as your dose of Zonisamide 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 water.**
- live in a place or are on holiday in a place where the weather is warm. Zonisamide 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.**
- are underweight or have lost a lot of weight as Zonisamide 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.

### **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:

- 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, your child 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 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 Other medicines). 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**

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

- Zonisamide 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 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.

### **Zonisamide Rosemont with food and drink**

Zonisamide Rosemont 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 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 and for one month after stopping zonisamide.

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.

#### Breast-feeding

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

#### Fertility

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 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 affects you in this way.

Zonisamide Rosemont contains sodium benzoate and sodium:

- Sodium benzoate (E211). This medicine contains 1 mg sodium benzoate (E211) in each ml.
- Sodium. This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

### **3. How to take Zonisamide Rosemont**

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 on its own:**

- The starting dose is 100 mg (5ml) taken once a day.
- This may be increased by up to 100 mg (5ml) at intervals of two weeks.
- The recommended dose is 300 mg (15ml) once a day.

##### **When you take Zonisamide with other antiepileptic medicines:**

- The starting dose is 50 mg (2.5ml) daily taken in two equal doses of 25 mg (2x 1.25ml/day).
- This may be increased by up to 100 mg (5ml) at intervals of one to two weeks.
- The recommended daily dose is between 300 mg and 500 mg (15 to 25 ml/day).
- 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 (0.05 ml) per kg of body weight taken once a day.
- This may be increased by 1 mg (0.05 ml) per kg of body weight at intervals of one to two weeks.
- The recommended daily dose is 6 to 8 mg (0.3 to 0.4 ml) per kg for a child with a body weight of up to 55 kg or 300 to 500 mg (15 to 25 ml) 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 (1.25ml) once a day for the first week, and then increase the daily dose by 25 mg (1.25ml) at the start of each week until a daily dose between 150 to 200 mg (7.5 to 10ml) is reached.*

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

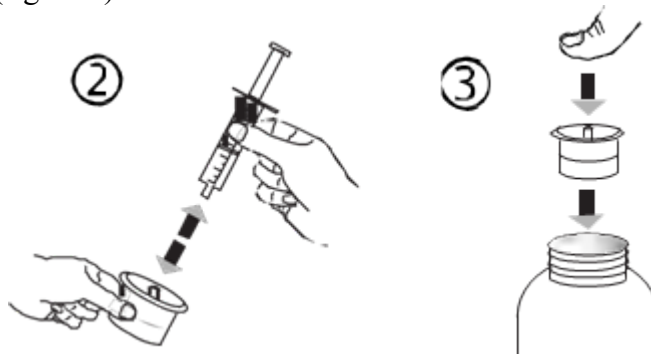
- Zonisamide can be taken once or twice daily, as instructed by your doctor.
- If you take Zonisamide twice a day, take half the daily dose in the morning and half in the evening.
- The oral suspension must be shaken well vigorously for 10 seconds before use.

### Instructions for use

- Open the bottle: press the cap and turn it anticlockwise (figure 1)



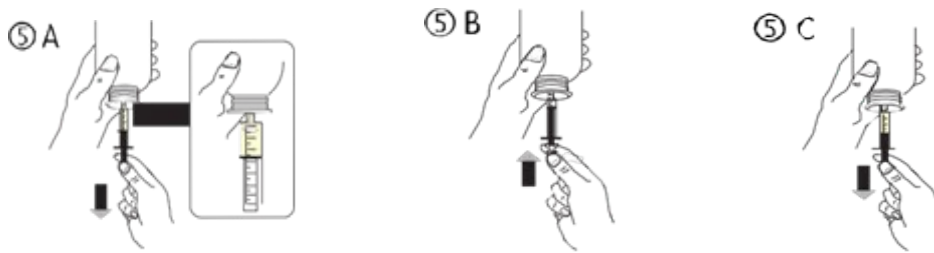
- Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is well fixed.



- Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).



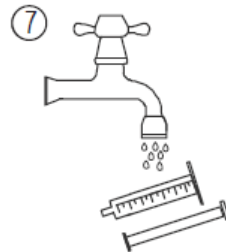
- Fill the syringe with a small amount of suspension by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).



- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- Close the bottle with the plastic screw cap.
- Empty the contents of the syringe into your mouth.
- After dosing, wash the syringe with water only (figure 7).



### **If you take more Zonisamide than you should**

If you may have taken more Zonisamide 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 heartbeat, and reduced breathing and kidney function. Do not try to drive.

### **If you forget to take Zonisamide**

- 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**

- Zonisamide 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 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.

### **Taking this medicine via NG or PEG tubes**

1. Ensure the tube is clear before taking the medicine.

2. Administer the medicine with a suitable measuring device, which will be provided by your doctor, pharmacist, or nurse. Do not use the oral syringe provided in the pack.
3. Flush the tube immediately with 10 ml of water three times.

#### **4. Possible side effects**

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

##### **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.

The most common side effects of Zonisamide 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 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](http://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 Rosemont**

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

Do not store above 25°C

Store in the original package in order to protect from light. Discard after 30 days of first opening.

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



Do not use this medicine if you notice that the suspension becomes discoloured or shows any signs of deterioration. Return the pack to your pharmacist.

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

## **6. Contents of the pack and other information**

### **What Zonisamide Rosemont contains**

The active substance in each ml of suspension is 20mg of Zonisamide.

The other ingredients are microcrystalline cellulose and carmellose sodium, sucralose (E955), xanthan gum (E415), sodium benzoate (E211), citric acid monohydrate (E 330), sodium citrate (E331), strawberry flavour (501099 A) and purified water.

### **What Zonisamide Rosemont looks like and contents of the pack**

White to off-white suspension.

Zonisamide Rosemont 20mg/ml Oral Suspension is packaged in 150ml amber PET bottle with a PP tamper-evident, child-resistant closure. The pack contains a 10ml polypropylene oral syringe (graduated every 0.25 ml from 1.0 ml onwards) together with LDPE adaptor.

### **The Marketing Authorisation Holder and Manufacturer is:**

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Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK. Tel: + 44 (0) 113 244 1400

#### **The Manufacturer is:**

LM Manufacturing Limited, Sandretto Building, Cavalry Hill Industrial Park, Weedon, Northampton, NN7 4PP, United Kingdom.

**This leaflet was last revised in September 2024**

**If you would like this leaflet in different format information, please contact marketing authorisation holder listed above.**