Package leaflet: Information for the patient

Zonisamide Neuraxpharm 25 mg tablets
Zonisamide Neuraxpharm 50 mg tablets
Zonisamide Neuraxpharm 100 mg tablets
Zonisamide Neuraxpharm 200 mg tablets
Zonisamide Neuraxpharm 300 mg tablets

zonisamide

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 Neuraxpharm is and what it is used for

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

Zonisamide Neuraxpharm 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 Neuraxpharm 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 Neuraxpharm

Do not take Zonisamide Neuraxpharm

- 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,

Warnings and precautions

Zonisamide Neuraxpharm 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 Neuraxpharm therapy, including cases of Stevens-Johnson syndrome.

The use of Zonisamide Neuraxpharm 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 Neuraxpharm 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 Neuraxpharm is not recommended for you.
- are elderly, as your dose of Zonisamide Neuraxpharm 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 Neuraxpharm (see section 4 Possible side effects).
- suffer from liver problems, as your dose of Zonisamide Neuraxpharm may need adjusting.
- have eye problems such as glaucoma.
- suffer from kidney problems as your dose of Zonisamide Neuraxpharm 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 Neuraxpharm 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 Neuraxpharm 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 Neuraxpharm.

Children and adolescents
Talk to your doctor about the following risks:

Preventing overheating and dehydration in children

Zonisamide Neuraxpharm 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 Neuraxpharm:

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

- Zonisamide Neuraxpharm 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 Neuraxpharm 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 Neuraxpharm, which may require an adjustment of your dose of Zonisamide Neuraxpharm.

Pregnancy, breast-feeding and fertility
If you are a woman of childbearing age you must use adequate contraception while taking and for one month after stopping Zonisamide Neuraxpharm.
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 your are or think you might be pregnant, tell your doctor straight away. You should not stop your treatment without discussing this with your doctor.

You must only take Zonisamide Neuraxpharm during your pregnancy if your doctor tells you to. Research has shown an increased risk of birth defects in children of women taking anti-epileptic medicines. The risk of birth defects or neurodevelopmental disorders (problems with brain development) for your child after taking Zonisamide Neuraxpharm during your pregnancy is unknown. A study showed 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 the benefits of using zonisamide for epilepsy during pregnancy.

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

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 Neuraxpharm 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 Neuraxpharm affects you in this way.

Zonisamide Neuraxpharm contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dose that is to say essentially "sodium - free".

3. How to take Zonisamide Neuraxpharm

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 Neuraxpharm *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 Neuraxpharm *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 (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 Neuraxpharm is too strong or too weak, talk to your doctor or pharmacist.

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

Zonisamide Neuraxpharm *25 mg, 50 mg, 100 mg, 200 mg, 300 mg tablets:*
The tablet can be divided into equal doses.

Method of administration
For oral use.
Zonisamide Neuraxpharm can be taken with or without food.

If you take more Zonisamide Neuraxpharm than you should

If you may have taken more Zonisamide Neuraxpharm 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 Neuraxpharm
- 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 Neuraxpharm
- Zonisamide Neuraxpharm 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 Neuraxpharm 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 Neuraxpharm 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 Neuraxpharm 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 Neuraxpharm.

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 Neuraxpharm.

The most common side effects of Zonisamide Neuraxpharm 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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zonisamide Neuraxpharm

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.

This medicine does not require any special storage conditions

Do not use this medicine if you notice any damage to the tablets, 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 Neuraxpharm contains
The active substance is zonisamide.

Each tablet contains 25 mg of zonisamide.
Each tablet contains 50 mg of zonisamide.
Each tablet contains 100 mg of zonisamide.
Each tablet contains 200 mg of zonisamide.
Each tablet contains 300 mg of zonisamide.

The other ingredients are: cellulose microcrystalline, lactose monohydrate, croscarmellose sodium, povidone K-25, sodium laurilsulfate, anhydrous colloidal silica, magnesium stearate.

What Zonisamide Neuraxpharm looks like and contents of the pack

- Zonisamide Neuraxpharm 25 mg are white, round biconvex scored tablets, with the inscription “N” debossed on one side, diameter: 5 mm.
- Zonisamide Neuraxpharm 50 mg are white, round biconvex scored tablets, with the inscription “N1” debossed on one side Diameter: 6.5 mm.
- Zonisamide Neuraxpharm 100 mg are white, round biconvex scored tablets, with the inscription “N2” debossed on one side Diameter: 9 mm.
- Zonisamide Neuraxpharm 200 mg are white, oblong biconvex scored tablets, with the inscription “N3” debossed on one side, size: 16 mm x 7 mm.
- Zonisamide Neuraxpharm 300 mg are white, oblong biconvex scored tablets, with the inscription “N7” debossed on one side, size: 17 mm x 8.5 mm.

Zonisamide Neuraxpharm is available in blisters containing 7, 14, 28, 56, 98 and 196 or multipacks containing 196 (2 packs of 98) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Neuraxpharm Ireland Limited
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Manufacturer:
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This medicine is authorised in the Member States of the European Economic Area under the following names:

DE/H/7106/001-005/DC:

Germany	Zonisamideneuraxpharm 25 mg, 50 mg, 100 mg, 200 mg, 300 mg Tabletten
France	Zonisamide neuraxpharm 25 mg, 50 mg, 100 mg, 200 mg, 300 mg comprimé sécable
Ireland	Zonisamide neuraxpharm 25 mg, 50 mg, 100 mg, 200 mg, 300 mg tablets
Czech Republic	Zonisamide neuraxpharm 25 mg, 50 mg, 100 mg, 200 mg, 300 mg tablety
Slovakia	Zonisamide neuraxpharm 25 mg, 50 mg, 100 mg, 200 mg, 300 mg tablety

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