

Package leaflet: Information for the patient

Zonisamide Desitin 20 mg/ml oral suspension 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 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 Desitin is and what it is used for
2. What you need to know before you take Zonisamide Desitin
3. How to take Zonisamide Desitin
4. Possible side effects
5. How to store Zonisamide Desitin
6. Contents of the pack and other information

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

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

Do not take Zonisamide Desitin:

- 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 Desitin 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 Desitin therapy, including cases of Stevens-Johnson syndrome.

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

Children and adolescents

Talk to your doctor about the following risks:

Preventing overheating and dehydration in children

Zonisamide Desitin 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 Desitin:

- 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 Desitin 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 Desitin

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Zonisamide Desitin 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 Desitin 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 Desitin, which may require an adjustment of your dose of Zonisamide Desitin.

Zonisamide Desitin with drink

Carbonated beverages such as mineral water should not be taken with Zonisamide Desitin (see section 3).

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 Desitin.

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.

You must only take Zonisamide Desitin 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 Desitin 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 Desitin.

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 Desitin 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 Desitin affects you in this way.

Zonisamide Desitin contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate

which may cause allergic reactions (possibly delayed).

Zonisamide Desitin contains Sulphur dioxide (E 220)

which may rarely cause severe hypersensitivity reactions and bronchospasm.

Zonisamide Desitin contains fructose.

This medicine contains 0,026 mg fructose in each dosing syringe (10 ml). Fructose may damage teeth.

Zonisamide Desitin contains Glucose and sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Glucose and sucrose may be harmful to the teeth.

Zonisamide Desitin contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per dosing syringe (10 ml), that is to say essentially 'sodium-free'.

3. How to take Zonisamide Desitin

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

The recommended adult dose:

When you take Zonisamide Desitin on its own:

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

When you take Zonisamide Desitin with other antiepileptic medicines:

- The starting dose is 50 mg daily taken in two equal doses of 25 mg (= 2x 1.25 ml/day).
- This may be increased by up to 100 mg (= 5 ml) at intervals of one to two weeks.
- The recommended daily dose is between 300 mg and 500 mg (= 15 – 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 – 0.4 ml) per kg for a child with a body weight of up to 55 kg or 300 to 500 mg (= 15 – 25 ml) for a child with a body weight more than 55 kg (which ever dose is lower) taken once a day.

Dose recommendation for children aged 6 years and above with a body weight between 20 and 55 kg

Body Weight	Initial Dose	Maintenance Dose
20 kg	20 mg/day = 1 ml/day	120 – 160 mg/day = 6 – 8 ml/day
25 kg	25 mg/day = 1.25 ml/day	150 – 200 mg/day = 7.5 – 10 ml/day
30 kg	30 mg/day = 1.5 ml/day	180 – 240 mg/day = 9 – 12 ml/day
35 kg	35 mg/day = 1.75 ml/day	210 – 280 mg/day = 10.5 – 14 ml/day
40 kg	40 mg/day = 2 ml/day	240 – 320 mg/day = 12 – 16 ml/day
45 kg	45 mg/day = 2.25 ml/day	270 – 360 mg/day = 13.5 – 18 ml/day
50 kg	50 mg/day = 2.5 ml/day	300 – 400 mg/day = 15 – 20 ml/day
55 kg	55 mg/day = 2.75 ml/day	330 – 440 mg/day = 16.5 – 22 ml/day

Example: A child who weighs 25 kg should take 25 mg (= 1.25 ml) once a day for the first week, and then increase the daily dose by 25 mg (= 1.25 ml) at the start of each week until a daily dose between 150 to 200 mg (= 7.5 – 10 ml) is reached.

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

Method and route of administration:

Shake the bottle vigorously for 30 seconds in a bottom up position. If a sediment is detected at the bottom of the bottle, shake the bottle for another 30 seconds. After measuring the correct dose with the provided syringe, Zonisamide Desitin may be swallowed directly from the oral syringe or diluted in a glass of water or orange juice. Carbonated beverages such as mineral water should not be taken with the suspension.

You may take Zonisamide Desitin with or without food. Zonisamide Desitin can be mixed with yoghurt to mask its taste.

The oral suspension may also be administered via a feeding tube that should be rinsed three times

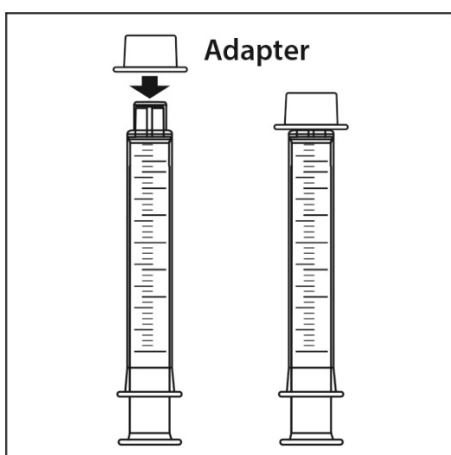
immediately after administration with at least 5 ml of water for each rinse. If this method of administration is used, the suspension should be prepared as described above for oral use immediately before administration.

INSTRUCTIONS FOR USE

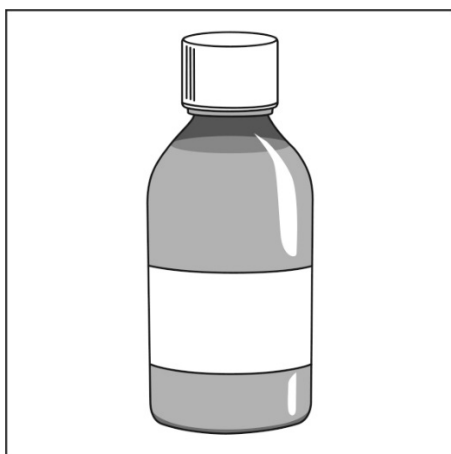
Read these instructions carefully so that you know how to use this medicine.

Components of the medicine kit

There are three parts to the medicine kit:



1. A plastic adapter and a 10 ml oral syringe which fits into the plastic adapter.

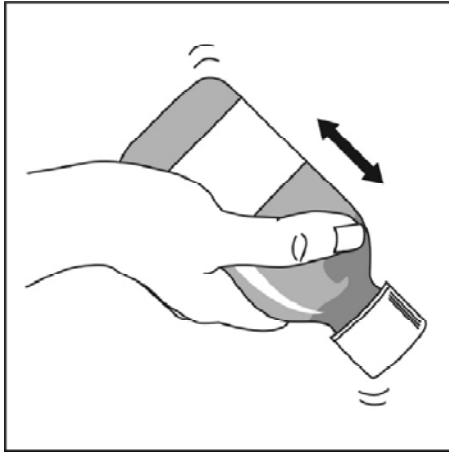


2. A bottle containing 250 ml of the medicine, with a child-resistant cap. Always replace the cap after use.

Preparing a dose of medicine

1. Shake the bottle vigorously for 30 seconds in a bottom up position. If a sediment is detected at the bottom of the bottle, shake the bottle for another 30 seconds.
2. Open the child-resistant cap by firmly pressing it down and twisting it anti-clockwise (see top of cap).

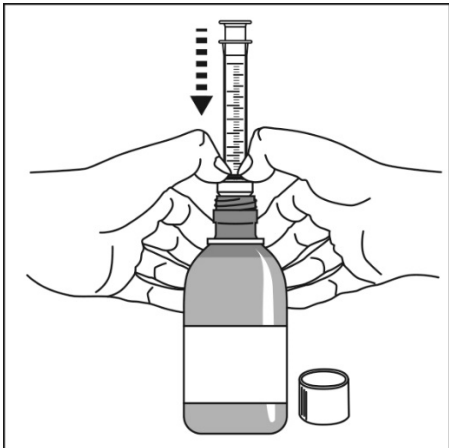
Note: Keep the cap nearby to close the bottle after each use.



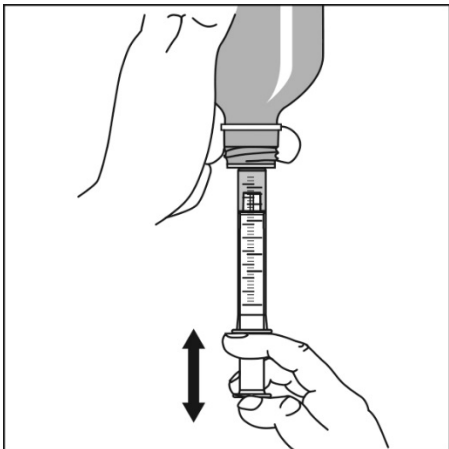
3. Hold the bottle upright on a table. Firmly push the plastic adapter with the oral syringe into the bottle opening, as far as you can.

Note: You may not be able to push the adapter down fully but it will be forced into the bottle when you screw the cap back on.

After the first use the adapter remains in the bottle.



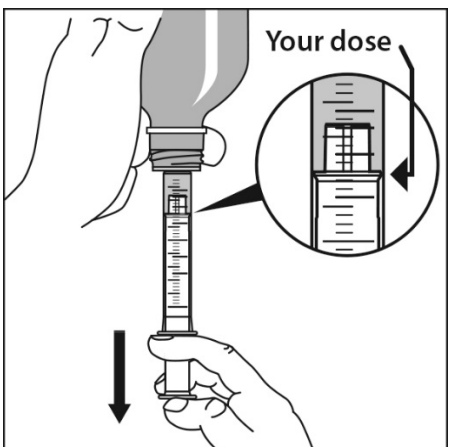
4. Hold the oral syringe in place and carefully turn the bottle upside down. Slowly pull out the plunger so that the oral syringe fills up with the suspension. Push the plunger back up completely to remove any large air bubbles that may be trapped inside the oral syringe.



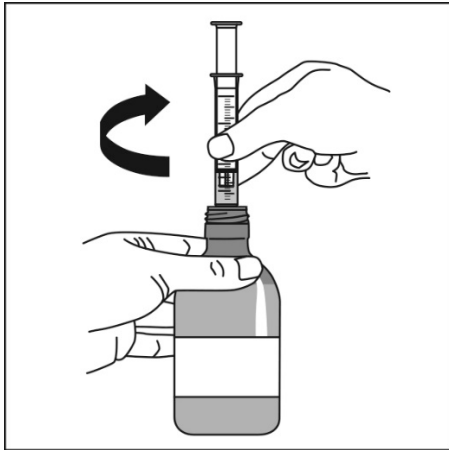
5. Drawing the prescribed dose: Slowly pull out the syringe plunger, until the top of the wider part of the plunger is exactly on a level with the marker on the oral syringe barrel that indicates the prescribed dose.

Note: If the prescribed dose is more than 10 ml, fill the oral syringe to the 10 ml mark, and take the 10 ml. **Then** reload the oral syringe to the required level to take the remaining amount.

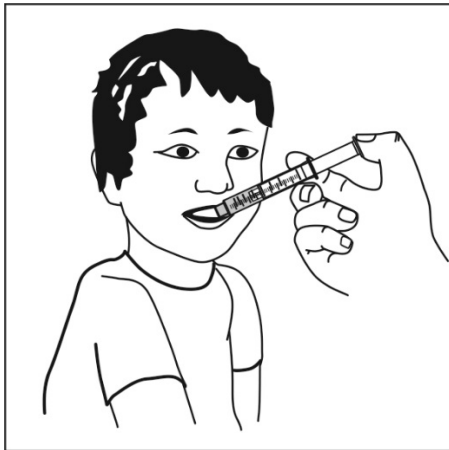
Ask your pharmacist if you are unsure.



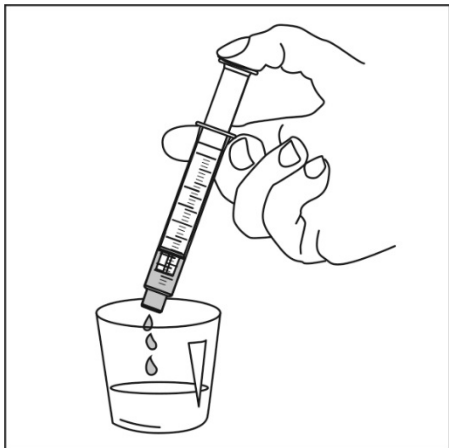
6. Carefully turn the bottle and oral syringe the right way up. Remove the oral syringe by carefully twisting it from out of the adapter. The adapter must always stay in the bottle.



7. Administer the dose directly into the mouth of the patient, who should be sitting in an upright position. Press the plunger slowly in order to allow for easy swallowing. The patient should drink a glass of water directly after intake.



Alternatively, the dose can be mixed in a small glass of water, orange juice or yoghurt just prior to administration. Stir and take the entire mixture right away.



8. Replace the child-resistant cap after use, leaving the adapter in place.

9. Cleaning: After use, wipe the outside of the syringe with a dry, clean tissue.

If you take more Zonisamide Desitin than you should

If you may have taken more Zonisamide Desitin 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 Desitin

- 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 Desitin

- Zonisamide Desitin 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 Desitin 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 Desitin 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 Desitin 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 Desitin.

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 taking Zonisamide Desitin.

The most common side effects of Zonisamide Desitin are mild. They occur during the first month of treatment and usually decrease with continued treatment. In children aged 6-17 years, 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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zonisamide Desitin

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 bottle and the box after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After opening do not use longer than 3 months.

Do not use this medicine if you notice any damage to the bottle, closure or carton. 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 Desitin contains

The active substance is zonisamide.

1 ml oral suspension contains 20 mg zonisamide.

The other ingredients are: Xanthan gum, sodium dihydrogen phosphate dihydrate, dipotassium phosphate, docusate sodium, sucralose, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), strawberry flavour (containing traces of sodium), sweetness modulator flavour (containing traces of fructose, glucose, sucrose, E220 and sodium), masking flavour (containing traces of sodium), phosphoric acid 85 %, purified water

What Zonisamide Desitin looks like and contents of the pack

Zonisamide Desitin oral suspension is a white liquid with strawberry taste.

1 glass bottle with 250 ml of Zonisamide Desitin oral suspension packed in a box containing an oral syringe of 10 ml graduated every 0.25 ml and an adapter.

2 glass bottles with 250 ml of Zonisamide Desitin oral suspension each packed in a box containing an oral syringe of 10 ml graduated every 0.25 ml and an adapter.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Desitin Arzneimittel GmbH
Weg beim Jäger 214
D-22335 Hamburg
Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark	Zonisamid Desitin
Finland	Zonisamide Desitin 20 mg/ml oraalisuspensio
Germany	Zonisamid Desitin 20 mg/ml Suspension zum Einnehmen
Ireland	Zonisamide Desitin 20 mg/ml oral suspension
Norway	Zonisamid Desitin
Romania	Zonisamidă Desitin 20 mg/ml suspensie orală

This leaflet was last revised in {MM/YYYY}