Package leaflet: Information for the patient

Zilibra 50 mg filmomhulde tabletten
Zilibra 100 mg filmomhulde tabletten
Zilibra 150 mg filmomhulde tabletten
Zilibra 200 mg filmomhulde tabletten

Lacosamide

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 Zilibra is and what it is used for

What Zilibra is
Zilibra contains lacosamide. This belongs to a group of medicines called “antiepileptic medicines”. These medicines are used to treat epilepsy.
- You have been given this medicine to lower the number of fits (seizures) you have.

What Zilibra is used for
Zilibra is used:
- on its own and in association with other antiepileptic medicines in adults, adolescents and children aged 2 years and older to treat a certain type of epilepsy characterised by the occurrence of partial-onset seizure with or without secondary generalisation. In this type of epilepsy, fits first affect only one side of your brain. However, these may then spread to larger areas on both sides of your brain;
- in association with other antiepileptic medicines in adults, adolescents and children aged 4 years and older to treat primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in patients with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

2. What you need to know before you take Zilibra

Do not take Zilibra
- if you are allergic to lacosamide, or any of the other ingredients of this medicine (listed in Section 6). If you are not sure whether you are allergic, please discuss with your doctor.
- if you have a certain type of heart beat problem called second- or third-degree AV block.

Do not take Zilibra if any of the above applies to you. If you are not sure, talk to your doctor or

pharmacist before taking this medicine.

Warning and precautions
Talk to your doctor before taking Zilibra if:

- you have thoughts of harming or killing yourself. A small number of people being treated with antiepileptic medicinal products such as lacosamide have had thoughts of harming or killing themselves. If you have any of these thoughts at any time, tell your doctor straight away.
- you have a heart problem that affects the beat of your heart and you often have a particularly slow, fast or irregular heart beat (such as AV block, atrial fibrillation and atrial flutter).
- you have severe heart disease such as heart failure or have had a heart attack.
- you are often dizzy or fall over. Zilibra may make you dizzy - this could increase the risk of accidental injury or a fall. This means that you should take care until you are used to the effects of this medicine.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Zilibra.
If you are taking Zilibra, talk to your doctor if you are experiencing a new type of seizure or worsening of existing seizures.
If you are taking Zilibra and you are experiencing symptoms of abnormal heartbeat (such as slow, rapid or irregular heartbeat, palpitations, shortness of breath, feeling lightheaded, fainting), seek medical advice immediately (see section 4).

Children
Zilibra is not recommended for children aged under 2 years with epilepsy characterised by the occurrence of partial-onset seizure and not recommended for children aged under 4 years with primary generalised tonic-clonic seizures. This is because we do not yet know whether it will work and whether it is safe for children in this age group.

Other medicines and Zilibra
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines that affect your heart. This is because Zilibra can also affect your heart:

- medicines to treat heart problems;
- medicines which can increase the "PR interval" on a scan of the heart (ECG or electrocardiogram) such as medicines for epilepsy or pain called carbamazepine, lamotrigine or pregabalin;
- medicines used to treat certain types of irregular heart beat or heart failure.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Zilibra.

Also tell your doctor or pharmacist if you are taking any of the following medicines - this is because they may increase or decrease the effect of Zilibra on your body:

- medicines for fungal infections such as fluconazole, itraconazole or ketoconazole;
- a medicine for HIV such as ritonavir;
- medicines used to treat bacterial infections such as clarithromycin or rifampicin;
- a herbal medicine used to treat mild anxiety and depression called St. John's wort.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Zilibra.

Zilibra with alcohol
As a safety precaution do not take Zilibra with alcohol.

Pregnancy and breast-feeding

Fertile women should discuss the use of contraceptives with the doctor.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not recommended to take Zilibra if you are pregnant, as the effects of Zilibra on pregnancy and the unborn baby are not known.
It is not recommended to breast-feed your baby while taking, Zilibra as Zilibra passes into breast milk.
Seek advice immediately from your doctor if you get pregnant or are planning to become pregnant. They will help you decide if you should take Zilibra or not.

Do not stop treatment without talking to your doctor first as this could increase your fits (seizures). A worsening of your disease can also harm your baby.

Driving and using machines
Do not drive, cycle or use any tools or machines until you know how this medicine affects you. This is because Zilibra may make you feel dizzy or cause blurred vision.

Zilibra 50 mg film-coated tablets contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Zilibra 200 mg film-coated tablets contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Zilibra

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Taking Zilibra
- Take Zilibra twice each day – approximately 12 hours apart.
- Try to take it at about the same time each day.
- Swallow the Zilibra tablet with a glass of water.
- You may take Zilibra with or without food.

You will usually start by taking a low dose each day and your doctor will slowly increase this over a number of weeks. When you reach the dose that works for you, this is called the "maintenance dose", you then take the same amount each day. Zilibra is used as a long term treatment. You should continue to take Zilibra until your doctor tells you to stop.

How much to take
Listed below are the normal recommended doses of Zilibra for different age groups and weights. Your doctor may prescribe a different dose if you have problems with your kidneys or with your liver.

Adolescents and children weighing 50 kg or more and adults
<u>When you take Zilibra on its own</u>
- The usual starting dose of Zilibra is 50 mg twice a day.
- Your doctor may also prescribe a starting dose of 100 mg of Zilibra twice a day.
- Your doctor may increase your twice daily dose every week by 50 mg. This will be until you reach a maintenance dose between 100 mg and 300 mg twice a day.

When you take Zilibra with other antiepileptic medicines

- The usual starting dose of Zilibra is 50 mg twice a day.
- Your doctor may increase your twice daily dose every week by 50 mg. This will be until you reach a maintenance dose between 100 mg and 200 mg twice a day.
- If you weigh 50 kg or more, your doctor may decide to start Zilibra treatment with a single "loading" dose of 200 mg. You would then start your ongoing maintenance dose 12 hours later.

Children and adolescent weighing less than 50 kg

- *In the treatment of partial-onset seizure*: Observe that Zilibra is not recommended for children under 2 years of age.
- *In the treatment of primary generalised tonic-clonic seizures*: Observe that Zilibra is not recommended for children under 4 years of age.

- The dose depends on their body weight. They usually start treatment with the syrup and only change to tablets if they are able to take tablets and get the correct dose with the different tablet strengths. The doctor will prescribe the formulation that is best suited to them.

If you take more Zilibra than you should

If you have taken more Zilibra than you should, contact your doctor immediately. Do not try to drive. You may experience:

- dizziness;
- feeling sick (nausea) or being sick (vomiting);
- fits (seizures), heart beat problems such a slow, fast or irregular heart beat, coma or a fall in blood pressure with rapid heartbeat and sweating.

If you forget to take Zilibra

- If you have missed a dose within the first 6 hours of the scheduled dose, take it as soon as you remember.
- If you have missed a dose beyond the first 6 hours of the scheduled dose, do not take the missed tablet anymore. Instead take Zilibra at the next time that you would normally take it.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Zilibra

- Do not stop taking Zilibra without talking to your doctor, as your epilepsy may come back again or become worse.
- If your doctor decides to stop your treatment with Zilibra, they will tell you how to decrease the dose step by step.

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.

Nervous system side effects such as dizziness may be higher after a single "loading" dose.

Talk to your doctor or pharmacist if you get any of the following:

Very common: may affect more than 1 in 10 people

- Headache;
- Feeling dizzy or sick (nausea);
- Double vision (diplopia).

Common: may affect up to 1 in 10 people

- Short jerks of a muscle or group of muscles (myoclonic seizures);
- Difficulties in coordinating your movements or walking;
- Problems in keeping your balance, shaking (tremor), tingling (paresthesia) or muscle spasms, falling easily and getting bruises;
- Troubles with your memory, thinking or finding words, confusion;
- Rapid and uncontrollable movements of the eyes (nystagmus), blurred vision;
- A spinning sensation (vertigo), feeling drunk;
- Being sick (vomiting), dry mouth, constipation, indigestion, excessive gas in the stomach or bowel, diarrhoea;
- Decreased feeling or sensitivity, difficulty in articulating words, disturbance in attention;
- Noise in the ear such as buzzing, ringing or whistling;
- Irritability, trouble sleeping, depression;
- Sleepiness, tiredness or weakness (asthenia);
- Itching, rash.

Uncommon: may affect up to 1 in 100 people
- Slow heart rate, palpitations, irregular pulse or other changes in the electrical activity of your heart (conduction disorder);
- Exaggerated feeling of wellbeing, seeing and/or hearing things which are not there;
- Allergic reaction to medicine intake, hives;
- Blood tests may show abnormal liver function , liver injury;
- Thoughts of harming or killing yourself or attempting suicide: tell your doctor straight away;
- Feeling angry or agitated;
- Abnormal thinking or losing touch with reality;
- Serious allergic reaction which causes swelling of the face, throat, hand, feet, ankles, or lower legs;
- Fainting;
- Abnormal involuntary movements (dyskinesia).

Not known: frequency cannot be estimated from available data
- Abnormal rapid heartbeat (ventricular tachyarrhythmia);

- A sore throat, high temperature and getting more infections than usual. Blood tests may show a severe decrease in a specific class of white blood cells (agranulocytosis);
- A serious skin reaction which may include a high temperature and other flu-like symptoms, a rash on the face, extended rash, swollen glands (enlarged lymph nodes). Blood tests may show increased levels of liver enzymes and a type of white blood cell (eosinophilia);
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome), and a more severe form causing skin peeling in more than 30 % of the body surface (toxic epidermal necrolysis);
- Convulsion.

Additional side effects in children
The additional side effects in children were fever (pyrexia), runny nose (nasopharyngitis), sore throat (pharyngitis), eating less than usual (decreased appetite), changes in behaviour, not acting like themselves (abnormal behavior) and lacking in energy (lethargy). Feeling sleepy (somnolence) is a very common side effect in children and may affect more than 1 in 10 children.

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 Zilibra

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 or 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 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 Zilibra contains

The active substance is lacosamide.
One tablet of Zilibra 50 mg contains 50 mg lacosamide.
One tablet of Zilibra 100 mg contains 100 mg lacosamide.
One tablet of Zilibra 150 mg contains 150 mg lacosamide.
One tablet of Zilibra 200 mg contains 200 mg lacosamide.

The other ingredients are:
Tablet core: microcrystalline cellulose, hydroxypropylcellulose, hydroxypropylcellulose (low substituted), silicified microstalline cellulose, crospovidone (type B), magnesium stearate

Film-coat: polyvinyl alcohol, polytheylene gylcol, talc, titanium dioxide (E171), colourants*
***** The colourants are:
50 mg tablet: red iron oxide (E172), black iron oxide (E172), indigo carmine aluminium lake (E132)
100 mg tablet: yellow iron oxide (E172)
150 mg tablet: yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172)
200 mg tablet: indigo carmine aluminium lake (E132)

What Zilibra looks like and contents of the pack
Zilibra 50 mg are pinkish, oval film-coated tablets, marked with ‘LAC’ on one side and ‘50’ on the other side.
Zilibra 100 mg are dark yellow, oval film-coated tablets, marked with ‘LAC’ on one side and ‘100’ on the other side.
Zilibra 150 mg are salmon, oval film-coated tablets, marked with ‘LAC’ on one side and ‘150’ on the other side.
Zilibra 200 mg are blue, oval film-coated tablets, marked with ‘LAC’ on one side and ‘200’ on the other side.

Zilibra is available in packs of 14, 56 and 84 film-coated tablets in clear, colourless PVC/PVDC blisters sealed with an aluminium foil.

Marketing Authorisation Holder
Pharmaceutical Works POLPHARMA SA
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83-200 Starogard Gdański

Polen

Manufacturer
Combino Pharm (Malta) Ltd.
HF60 Hal Far Industrial Estate, BBG3000
Malta

SVUS Pharma a.s.
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Tsjechische Republiek

Simvis Pharmaceuticals S.A.
Asklipiou 4-6, Kryoneri
Attiki, 14568, Griekenland

In het register ingeschreven onder:
Zilibra 50 mg filmomhulde tabletten - RVG 120254
Zilibra 100 mg filmomhulde tabletten - RVG 120259
Zilibra 150 mg filmomhulde tabletten - RVG 120260
Zilibra 200 mg filmomhulde tabletten - RVG 120261

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:
Nederland
Zilibra 50 mg filmomhulde tabletten
Zilibra 100 mg filmomhulde tabletten
Zilibra 150 mg filmomhulde tabletten
Zilibra 200 mg filmomhulde tabletten

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.