

Patient leaflet in accordance with the Pharmacists' regulations (preparations) - 1986

The medicine is to be supplied upon a physician's prescription only

Vimpat[®] 50 mg film-coated tablets
Vimpat[®] 100 mg film-coated tablets
Vimpat[®] 150 mg film-coated tablets
Vimpat[®] 200 mg film-coated tablets

Each film-coated Vimpat tablet contains Lacosamide 50 mg, 100 mg, 150 mg or 200 mg.

For information regarding the excipients see section 6 "Additional information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

Epilepsy is an illness characterized by repeated fits (seizures). Vimpat is administered when the state of epilepsy in which the fits are initially partial (affecting only one side of the brain), but may develop into generalised fits (affecting larger areas on both sides of the brain). Treatment with Vimpat is long-term. Do not stop treatment without an explicit instruction from the physician. Discontinuation of treatment may cause a recurrence or worsening of the illness' symptoms. See section "**If you stop taking the medicine**".

1. WHAT IS THE MEDICINE INTENDED FOR?

- Vimpat is used in adults, adolescents and children aged 4 years and older.
- Vimpat is indicated for the treatment of a certain type of epilepsy characterised by the occurrence of "partial-onset seizure with or without secondary generalisation".
- Vimpat may be used on its own or with other antiepileptic medicines.

Vimpat contains lacosamide. This belongs to a group of medicines called "antiepileptic medicines". These medicines are used to treat epilepsy.

Therapeutic group: Anticonvulsant.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, or to any of the other ingredients of the medicine (see section 6 "Additional Information"). If you are not sure whether you are allergic, please discuss with your doctor.
- You have a certain type of heartbeat problem called second- or third-degree AV block.

Do not take Vimpat if any of the above applies to you. If you are not sure, talk to your physician or pharmacist before taking this medicine.

Special warnings regarding the use of the medicine:

Do not use the medicine without consulting a physician before starting treatment

- 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 physician straight away.
- If you have a heart problem that affects the beat of your heart and you often have a particularly slow, fast or irregular heartbeat (such as AV block, atrial fibrillation or atrial flutter).
- If you have severe heart disease such as heart failure or have had a heart attack.

- If you are often dizzy or fall over. Vimpat may make you dizzy and this could increase the risk of accidental injury or a fall. This means that you should take care until you get used to the effects of this medicine.

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

If you are taking Vimpat and you are experiencing symptoms of abnormal heartbeat (such as slow, rapid or irregular heartbeat, palpitations, shortness of breath, feeling dizzy, fainting), seek medical advice immediately (see section 4).

Children under 4 years

Vimpat is not recommended for children aged under 4 years. This is because it is yet unknown whether Vimpat will work and whether Vimpat is safe for children in this age group.

Interaction with other medicinal products:

If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. It is especially important to inform the physician or pharmacist if you are taking any of the following medicines that affect your heart, this is because Vimpat can also affect your heart:

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

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

It is also especially important to inform the physician or pharmacist if you are taking any of the following medicines, this is because they may increase or decrease the effect of Vimpat on your body:

- Medicines for fungal infections called fluconazole, itraconazole or ketoconazole.
- A medicine for HIV called ritonavir.
- Medicines used to treat bacterial infections called clarithromycin or rifampicin.
- An 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 physician or pharmacist before taking Vimpat.

Use of the medicine and food

The medicine may be taken with or without food.

Use of the medicine and alcohol consumption

As a safety precaution, do not take Vimpat 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 planning to have a baby, ask your physician or pharmacist for advice before taking this medicine.

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

Do not stop treatment without talking to your physician 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 Vimpat may make you feel dizzy or cause blurred vision.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the physician's instructions. Check with the physician or pharmacist if you are unsure about your dosage or treatment regimen.

Dosage

The dosage and treatment regimen will be determined by the physician only.

- Take Vimpat twice each day - once in the morning and once in the evening
- Try to take the medicine at about the same time each day
- Swallow the Vimpat tablet with a glass of water

You will usually start by taking a low dose each day and your physician 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. Vimpat is used as a long term treatment. You should continue to take Vimpat until your physician tells you to stop.

How much to take

Listed below are the normal recommended doses of Vimpat for different age groups and weights. Your physician 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

When you take Vimpat on its own:

The usual starting dose of Vimpat is 50 mg twice a day.

Your physician may also prescribe a starting dose of 100 mg of Vimpat twice a day.

Your physician 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 Vimpat with other antiepileptic medicines:

The usual starting dose of Vimpat is 50 mg twice a day.

Your physician 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 physician may decide to start Vimpat treatment with a single loading dose of 200 mg. You would then start your ongoing maintenance dose 12 hours later.

Children and adolescents weighing less than 50 kg

The dose depends on their body weight. Children will receive treatment with tablets only if they are able to take tablets and get the correct dose with the different tablet strengths. Alternatively, and as appears later in the "crushing/splitting/chewing" section, if necessary, the tablet may be crushed and immediately swallowed with water. If a different dosage is required, consult with your doctor to determine the appropriate dosage and form of administration. The medicine is also registered in Israel as a solution for intravenous injection.

Do not exceed the recommended dose.

Instructions for use

Crushing/splitting/chewing

Do not split the tablets. There is no score line, therefore you cannot guarantee uniformity of both parts. To make swallowing easier, if necessary, the tablet may be crushed and immediately swallowed with water. The crushed tablet may have a bitter taste.

Duration of treatment

Vimpat is intended for long-term treatment.

You should complete the treatment recommended by the physician. Do not stop the treatment without a physician's instruction.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child accidentally swallowed this medicine, proceed to a physician or a hospital emergency room immediately and bring the package of the medicine with you. Do not try to drive.

You may experience:

- Dizziness
- Nausea or vomiting
- Fits (seizures), heartbeat problems such as slow, fast or irregular heartbeat, coma or a fall in blood pressure with rapid heartbeat and sweating.

If you forgot to take the medicine

- 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 dose anymore. Instead, take Vimpat 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 the medicine

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

You should continue the treatment as recommended by the physician.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the physician.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Vimpat may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

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

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

Very common side effects (may affect more than 1 in 10 patients):

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

Common side effects (may affect up to 1 in 10 patients):

- Problems in keeping your balance, shaking (tremor), tingling (paresthesia) or muscle spasm, 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, diarrhea
- 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 side effects (may affect up to 1 in 100 patients):

- 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 physician straight away
- Feeling angry or agitated
- Abnormal thinking or losing touch with reality
- Serious allergic reaction which causes swelling of the face, throat, hands, feet, ankles, or lower legs
- Fainting
- Abnormal involuntary movements (dyskinesia)
- Difficulty in coordinating movements or walking

Side effects of unknown frequency (frequency cannot be determined from the available data):

- Abnormal heartbeat (ventricular tachycardia)
- A sore throat, high fever 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 fever 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 cells (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

Fever, runny nose (nasopharyngitis), sore throat (pharyngitis), eating less than usual, changes in behaviour (not acting like themselves), lack in energy (lethargy). Feeling sleepy is a very common side effect in children and may affect more than 1 in 10 children.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult a physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects, or by the following link: <https://sideeffects.health.gov.il>

In addition, you can report to the Registration Holder's Patient Safety Unit by mail: drugsafety@neopharmgroup.com

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package and blister. The expiry date refers to the last day of that month.
- **Storage conditions:**
Store below 30°C.
Store in the original package.

- 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. ADDITIONAL INFORMATION

- **In addition to the active ingredient, the medicine also contains:**
Silicified microcrystalline cellulose, Cellulose microcrystalline, Hydroxypropylcellulose – low substituted, Crospovidone, Magnesium stearate, Hydroxypropylcellulose.

In addition, the film-coat contains:

Vimpat 50 mg:

Opadry 85F20249: Polyvinyl alcohol, Polyethylene glycol, Talc, Titanium dioxide, Red iron oxide, Black iron oxide, Indigo carmine aluminium lake.

Vimpat 100 mg:

Opadry 85F38040: Polyvinyl alcohol, Polyethylene glycol, Talc, Titanium dioxide, Yellow iron oxide.

Vimpat 150 mg:

Opadry 85F27043: Polyvinyl alcohol, Polyethylene glycol, Talc, Titanium dioxide, Yellow iron oxide, Red iron oxide, Black iron oxide.

Vimpat 200 mg:

Opadry 85F30675: Polyvinyl alcohol, Polyethylene glycol, Talc, Titanium dioxide, Indigo carmine aluminium lake.

- **What does the medicine look like and what are the contents of the package:**
Vimpat 50 mg tablets are pinkish, oval film-coated tablets of approximately 10.4 mm x 4.9 mm with a debossed 'SP' on one side and '50' on the other side.
Vimpat 100 mg tablets are dark yellow, oval film-coated tablets of approximately 13.2 mm x 6.1 mm with a debossed 'SP' on one side and '100' on the other side.
Vimpat 150 mg tablets are salmon-colored (pink-orange), oval film-coated tablets of approximately 15.1 mm x 7.0 mm with a debossed 'SP' on one side and '150' on the other side.
Vimpat 200 mg tablets are blue, oval film-coated tablets of approximately 16.6 mm x 7.8 mm with a debossed 'SP' on one side and '200' on the other side.

Vimpat is available in packs of 14, 56 film-coated tablets and in multipacks comprising 3 cartons, each containing 56 tablets. The packs are available with PVC/PVDC blisters sealed with an aluminium foil. Not all pack sizes may be marketed.

- **Manufacturer's name and address:**
UCB Pharma S.A., Bruxelles, Belgium.
- **Registration holder's name and address:**
Neopharm LTD., Hashiloach 6, P.O.Box 7063, Petach Tikva 4917001.
- Revised in November 2022 according to MOH guidelines.
- **Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:**
Vimpat® 50 mg film-coated tablets: 149-09-33546
Vimpat® 100 mg film-coated tablets: 149-10-33548
Vimpat® 150 mg film-coated tablets: 149-11-33551
Vimpat® 200 mg film-coated tablets: 149-12-33549

