

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**



VIMPAT®

50 mg/100 mg/150 mg/200 mg
film-coated tablets
Lacosamide

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Vimpat is and what it is used for
2. Before you take Vimpat
3. How to take Vimpat
4. Possible side effects
5. How to store Vimpat
6. Further information

1. WHAT VIMPAT IS AND WHAT IT IS USED FOR

Vimpat is used to treat a certain form of epilepsy (see below) in patients aged 16 years and older. Vimpat is used in addition to other antiepileptic medicines.

Epilepsy is a condition where the patients have repeated fits (seizures). Vimpat is used for the epilepsy form in which the fits initially affect only one side of the brain, but could thereafter extend to larger areas on both sides of the brain (partial onset seizure with or without secondary generalisation).

2. BEFORE YOU TAKE VIMPAT

Do NOT take Vimpat

- if you are allergic (hypersensitive) to lacosamide, or any of the other ingredients of Vimpat (listed in Section 6). If you are not sure whether you are allergic, please discuss with your doctor
- if you suffer from a certain type of heart rhythm disorder (second or third degree AV block)

Take special care with Vimpat

Please inform your doctor about the following:

- if you are taking any medicine which can cause an abnormality on the ECG (electrocardiogram) called increased PR interval, for example medicines used to treat certain types of irregular heart beat or heart failure. If you are not sure if the medicines you are taking could have this effect, discuss this with your doctor.

- if you suffer from a condition that is associated with impaired electric conduction across the heart or from severe heart disease such as heart failure or heart attack

Vimpat may cause dizziness, which could increase the risk of accidental injury or a fall. Therefore, you should be careful until you are used to the effects this medicine might have.

A small number of people being treated with anti-epileptics such as lacosamide have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important if you take medicines to treat heart problems (see also above "Take special care").

Taking Vimpat with food and drink

You may take Vimpat with or without food.

It is not advisable to drink alcohol while you are under treatment with Vimpat, because Vimpat could make you feel tired or dizzy. Drinking alcohol could make these effects worse.

Pregnancy and breast-feeding

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. Tell your doctor immediately if you are pregnant or planning to become pregnant; he/she will decide if you should take Vimpat.



It is not recommended to breast-feed your baby while taking Vimpat, as it is not known if Vimpat passes into the breast milk. If you are breast-feeding, please inform your doctor immediately; he/she will decide if you should take Vimpat.

Research has shown an increased risk of birth defects in children of women taking anti-epileptic medicines. On the other hand effective anti-epileptic therapy must not be interrupted since the worsening of the disease is harmful to both the mother and the unborn child.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Vimpat may cause dizziness or blurred vision. This may affect your ability to drive or operate any tools or machinery. You should not drive or use machines until you know whether this medicine affects your ability to perform these activities.

3. HOW TO TAKE VIMPAT

Always take Vimpat exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage

Vimpat must be taken twice a day, once in the morning and once in the evening, at about the same time each day. Vimpat is used as a long term treatment.

The usual starting dose of Vimpat is 100 mg per day - taken twice a day - 50 mg in the morning and 50 mg in the evening. Your doctor may increase your daily dose every week by 100 mg, until you reach a so called maintenance dose between 200 mg and

400 mg per day, taken twice a day. **You will use this maintenance dose for the long term treatment.**

Your doctor may prescribe you a **different dose** if you have problems with your kidneys.

How to take the Vimpat tablets

You should **swallow** the Vimpat tablet **with a glass of water**. You may take Vimpat with or without food.

Duration of the treatment with Vimpat

Vimpat is used as a long term treatment. You should continue to take Vimpat until your doctor tells you to stop.

If you take more Vimpat than you should

If you have taken more Vimpat than you should, **contact your doctor.**

If you forget to take Vimpat

If you miss a dose by a few hours, take it as soon as you remember. If it is close to your next dose, **don't take the missed tablet anymore. Just 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 Vimpat

Do not stop taking Vimpat without talking to your doctor, as your symptoms may come back again or become worse.

If your doctor decides to stop your treatment with Vimpat, he/she will instruct you about how you should decrease the dose step by step.

If you have any further questions on the use of this product, ask your doctor or pharmacist.



4. POSSIBLE SIDE EFFECTS

Like all medicines, Vimpat can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)

common (affects 1 to 10 users in 100)

uncommon (affects 1 to 10 users in 1,000)

rare (affects 1 to 10 users in 10,000)

very rare (affects less than 1 user in 10,000)

not known (frequency cannot be estimated from the available data)

Very common: affects more than 1 user in 10

- Dizziness, headache
- Nausea (feeling sick)
- Double vision (diplopia)

Common: affects 1 to 10 users in 100

- Problems in keeping your balance, difficulties in coordinating your movements, troubles with your memory, sleepiness, shaking (tremor), trouble thinking or finding words, rapid and uncontrollable movements of the eyes (nystagmus)
- Blurred vision
- A feeling of "spinning" (vertigo)
- Vomiting, constipation, excessive gas in the stomach or bowel
- Itching
- Fall
- Tiredness, difficulties in walking, unusual tiredness and weakness (asthenia)
- Depression

- Confusion
- Decreased feeling or sensitivity, difficulty in articulating words, disturbance in attention
- Noise in the ear such as buzzing, ringing or whistling
- Indigestion, dry mouth
- Irritability
- Muscle spasms
- Rash
- Trouble sleeping

Uncommon: affects 1 to 10 users in 1000

- Slow heart rate
- Heart conduction disorder
- Exaggerated feeling of wellbeing
- Allergic reaction to drug intake
- Liver function test abnormal
- Attempt to commit suicide
- Thoughts about suicide or hurting yourself
- Palpitations and/or rapid or irregular pulse
- Aggression
- Agitation
- Abnormal thinking and/or loss of touch with reality
- Serious allergic reaction which causes swelling of the face, throat, hand, feet, ankles, or lower legs
- Hives

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE VIMPAT

Keep out of the reach and sight of children.

Do not use Vimpat after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Vimpat contains

The active substance is lacosamide.

One tablet of Vimpat 50 mg contains 50 mg lacosamide.

One tablet of Vimpat 100 mg contains 100 mg lacosamide.

One tablet of Vimpat 150 mg contains 150 mg lacosamide.

One tablet of Vimpat 200 mg contains 200 mg lacosamide.

The other ingredients are:

Tablet core:

microcrystalline cellulose, hydroxypropylcellulose, hydroxypropylcellulose (low substituted), colloidal anhydrous silica, crospovidone, magnesium stearate

Film-coat:

polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide (E171), colourants*