

Vimpat®

injection (pronounced "vim-PAT")

Contains the active ingredient *lacosamide* (pronounced "la-KOE-sa-mide")

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Vimpat.

It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Vimpat against the expected benefits it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet in a safe place.

You may need to read it again.

What Vimpat is used for

Vimpat injection is used in patients over 4 years in combination with other medicines to control epilepsy. Vimpat injection can only be used by itself in patients over 16 years. Epilepsy is a condition where you have repeated seizures. There are many different types of seizures, ranging from mild to severe.

This medicine belongs to a group of medicines called antiepileptics. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no evidence that Vimpat is addictive.

This medicine is available only with a doctor's prescription.

Vimpat is not recommended for use in children under the age of 4 years as its safety and effectiveness has not been established in this age group.

Before you are given Vimpat

When you must not be given it

You must not be given Vimpat if you have an allergy to:

- Lacosamide or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You should not be given Vimpat if you have, or have had, a heart condition causing an uneven heart beat.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you:

- are taking any other medicines, especially barbiturates (such as phenobarbitone) or any other antiepileptic medicines (such as

carbamazepine, lamotrigine or levetiracetam)

- have allergies to any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- heart problems
- kidney problems
- liver problems
- any mental health condition, such as depression.

Tell your doctor if you are pregnant or intend to become pregnant.

Vimpat may affect your developing baby if you take it during pregnancy. However, it is very important to control your seizures while you are pregnant. Your doctor will weigh up all the risks and benefits of taking Vimpat during pregnancy to help decide whether or not you should be given it.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of using Vimpat during breastfeeding.

If you have not told your doctor about any of the above, tell them before you start taking Vimpat.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Vimpat may interfere with each other. These include:

- medicines to treat heart problems
- medicine which may have an effect on your heart beat such as carbamazepine, lamotrigine or pregabalin.

Vimpat does not interact with the oral contraceptive pill.

However, you may be given Vimpat together with other antiepileptic medicines that do interact and they may affect the effectiveness of your contraceptive. Your doctor may advise you to use an additional method of contraception if you take Vimpat with other antiepileptic medicines.

How Vimpat Injection is given

Vimpat Injection will be given to you by a doctor or nurse as a slow injection or infusion (drip) into a vein.

The amount of Vimpat you will be given will depend on your condition, body weight and whether or not you are taking any other medicines.

Your doctor may start you on a low dose of Vimpat first of 50 mg or 100 mg twice a day. Your doctor may slowly increase your dose up until a maximum of 300 mg twice a day, until you are taking enough to control your epilepsy and you are not having any seizures.

For use in children weighing less than 50kg, the doctor may start you on a low dose of Vimpat injection first of 0.1 mL/kg twice a day. The doctor may slowly increase your dose up to a maximum of 0.6 mL/kg twice a

day, until you are taking enough to control your epilepsy and you are not having any seizures.

If you are given too much (overdose)

As Vimpat Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given Vimpat, tell your doctor immediately or go to Accident and Emergency at the nearest hospital. You may need urgent medical attention.

In case of overdose, immediately contact the Poisons Information Centre for advice (telephone in Australia 13 11 26, in New Zealand 0800 POISON or 0800746 766).

While you are being given Vimpat

Things you must do

Tell your doctor immediately if you notice an increase in seizures.

Tell your doctor immediately if you have symptoms of depression or thoughts of harming yourself.

Tell any other doctors, dentists or pharmacists who are treating you that you are taking this medicine.

If you are about to be started on a new medicine, tell your doctor or dentist that you are taking Vimpat.

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking Vimpat.

Tell your doctor if you feel Vimpat is not helping your condition.

Your doctor may need to change your medicine.

If you become pregnant while taking this medicine, tell your doctor.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some tests from time to time. This helps to prevent unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how Vimpat affects you.

As with other antiepileptic medicines Vimpat may cause dizziness or drowsiness. This is more frequent at the beginning of treatment or after an increase in the dose.

If you are feeling dizzy or drowsy, do not drive a car, operate machinery, or do anything else that could be dangerous.

As a safety precaution, do not take Vimpat with alcohol.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are taking Vimpat.

This medicine helps most people with epilepsy but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You

may need medical treatment if you get some of the side effects.

Do not be alarmed by the list of side effects.

You may not experience any of them.

Ask your doctor to answer any questions you may have.

If you get any side effects, do not stop taking Vimpat without first talking to your doctor.

Tell your doctor or nurse if you notice any of the following and they worry you:

- dizziness or problems with balance coordination
- headache
- nausea (feeling sick) or vomiting
- feeling tired, drowsy or sleepy
- forgetfulness
- tremors
- itching
- redness, itchiness, pain or discomfort at the injection site.

The above list includes the more common side effects of your medicine. They are mostly mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- feelings of depression
- feeling aggressive or agitated
- spinning sensations
- double vision or blurred vision
- having trouble sleeping.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital:

- thoughts of harming yourself
- more frequent seizures or more severe seizures
- fainting or feeling lightheaded
- heart palpitations or a rapid or irregular pulse
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

The above list includes more serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After being given Vimpat

Storage

Vimpat Injection will be stored in the pharmacy or on the hospital ward. It is kept in a cool dry place where the temperature stays below 25°C.

Product description

What it looks like

Vimpat injection is a clear and colourless solution available in a 200 mg/20 mL strength in a glass vial.

Ingredients

Vimpat Injection contains 200 mg/20 mL lacosamide as the active ingredient. It also contains:

- sodium chloride
- hydrochloric acid (to adjust pH to 4.0)
- water for injections.

Australian Sponsor:

UCB Pharma
A division of UCB Australia Pty Ltd
Level 1, 1155 Malvern Road
Malvern Vic 3144,
Australia

NZ Sponsor:

Seqirus (NZ) Ltd
PO Box 62 590
Greenlane
Auckland 1546
Phone: 0800 502 757
Vimpat 200 mg/20 mL injection - AUST R
151815

Date of preparation:

March 2021

VIMPAT is a registered trademark used by UCB Pharma GmbH under license.