

Vimpat® Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given Vimpat®?

Vimpat® contains the active ingredient lacosamide. Vimpat® is used to control epilepsy in patients.

For more information, see Section [1. Why am I being given Vimpat®?](#) in the full CMI.

2. What should I know before I am given Vimpat®?

You must not be given Vimpat® if you have ever had an allergic reaction to lacosamide or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I am given Vimpat®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Vimpat® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given Vimpat®?

- 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 you are taking any other medicines. More information can be found in Section [4. How am I given Vimpat®?](#) in the full CMI.

5. What should I know while on Vimpat®?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using barbiturates (such as phenobarbitone), or any other antiepileptic medicines (such as carbamazepine, lamotrigine or levetiracetam) • Notify your doctor straightaway if you; • have increase of seizures or, • have symptoms of depression or thoughts of harming yourself.
Driving or using machines	• Vimpat® may cause dizziness and 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.
Drinking alcohol	• As a safety precaution, do not take Vimpat® with alcohol
Looking after your medicine	• 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.

For more information, see Section [5. What should I know while on Vimpat®?](#) in the full CMI.

6. Are there any side effects?

- Common side effects include dizziness or problems with balance or coordination headache nausea (feeling sick) or vomiting feeling tired, drowsy or sleepy forgetfulness tremors and itching.
- Serious side effects include depression, thoughts of harming yourself, more frequent seizures, fainting or feeling lightheaded and heart palpitations or a rapid or irregular pulse.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Vimpat® Injection (phonetic pronunciation – “vim-PAT”)

Active ingredient(s): *lacosamide* (phonetic pronunciation – “la-KOE-sa-mide”)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Vimpat®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Vimpat®.**

Where to find information in this leaflet:

1. [Why am I being given Vimpat®?](#)
2. [What should I know before I am given Vimpat®?](#)
3. [What if I am taking other medicines?](#)
4. [How am I given Vimpat®?](#)
5. [What should I know while on Vimpat®?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given Vimpat®?

Vimpat® contains the active ingredient lacosamide.

Vimpat® is an antiepileptic. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Vimpat® is used in patients to control epilepsy. Epilepsy is a condition where you have repeated seizures. There are many different types of seizures, ranging from mild to severe.

2. What should I know before I am given Vimpat®?

Warnings

Do not use Vimpat® if:

- You are allergic to lacosamide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.
- If you have a heart condition causing an uneven heartbeat.

Check with your doctor if you:

- Have any other medical conditions such as;
 - o heart problems,
 - o kidney problems,
 - o liver problems,
 - o and any other mental health condition, such as depression.
- take any medicines for any other condition especially;
 - o barbiturates (such as phenobarbitone)
 - o or any other antiepileptic medicines (such as carbamazepine, lamotrigine or levetiracetam)
 - o have allergies to any other substances, such as foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. 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 outline and weigh up all the risks and benefits of taking Vimpat® during pregnancy and/or breastfeeding to help decide whether or not you should take it.

Children and Adolescents

- 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.
- Vimpat® is used in combination with other medicines to control epilepsy in children 4 to 16 years of age.

Adolescents and Adults

- Vimpat® can only be used by itself in patients over the age of 16 years.

3. What if I am taking other medicines?

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

Some medicines may interfere with Vimpat® and affect how it works.

These medicines include;

- medicines to treat heart problems,
- and medicine which may have an effect on your heartbeat 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 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Vimpat®.

4. How am I given Vimpat®?

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 too much Vimpat® is given

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 an overdose, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while on Vimpat®?

Things you should do:

Call your doctor straight away if you:

- if you notice an increase in seizures.
- If you have symptoms of depression or thoughts of harming yourself.
- If you are about to start on any new medicine, tell your doctor, dentist or pharmacist 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.
- Remind any doctor, dentist or pharmacist you visit that you are taking Vimpat®.

Things you should not do

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Vimpat® affects you.

Vimpat® may cause dizziness and drowsiness, like other antiepileptic medicines. 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

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.

Keep it out of reach of young children.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Nervous system related: • dizziness or problems with balance or coordination • headache • forgetfulness • tremors • feelings of depression • feeling aggressive or agitated • spinning sensations • having trouble sleeping Vision related: • double vision or blurred vision	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
Digestion system related: - nausea (feeling sick) or vomiting Other: - feeling tired, drowsy or sleepy - itchiness	

Serious side effects

Serious side effects	What to do
Nervous system related: - thoughts of harming yourself - more frequent or more severe seizures - fainting or feeling lightheaded Heart related: - heart palpitations or a rapid or irregular pulse Allergic reaction related: - 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.	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or Medsafe (New Zealand) at <https://www.medsafe.govt.nz/safety/report-a-problem.asp> by reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Vimpat® contains

Active ingredient (main ingredient)	lacosamide
Other ingredients (inactive ingredients)	sodium chloride hydrochloric acid (to adjust pH to 4.0) water for injection

Do not take this medicine if you are allergic to any of these ingredients.

What Vimpat® looks like:

- Vimpat® Injection vial 200 mg/20 mL AUST R 151815

Who distributes Vimpat®

Australian Sponsor:

UCB Pharma

A division of UCB Australia Pty Ltd

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