

Epilim® IV

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 Epilim IV?

Epilim IV contains the active ingredient sodium valproate. Epilim IV is used for the treatment of epilepsy in adults and children.

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

2. What should I know before I am given Epilim IV?

You should not be given Epilim IV if you have ever had an allergic reaction to Epilim IV 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 Epilim IV?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Epilim IV 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 Epilim IV?

- If you are not currently taking Epilim or any other form of sodium valproate by mouth, your doctor will decide what dose you will receive, depending on your condition and other factors such as your weight.
- Epilim IV will be given to you as an infusion or injection into the veins.

More instructions can be found in Section [4. How am I given Epilim IV?](#) in the full CMI.

5. What should I know while I am being given Epilim IV?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Epilim IV.• If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.• If you become pregnant while you are taking this medicine, tell your doctor immediately
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or lower the dosage, without checking with your doctor.• Do not take more than the recommended dose unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Epilim IV affects you.• Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.
Drinking alcohol	<ul style="list-style-type: none">• The effects of alcohol could be made worse while taking Epilim IV.• Combining Epilim IV and alcohol can make you more sleepy, dizzy or lightheaded.
Looking after your medicine	<ul style="list-style-type: none">• If you need to store Epilim IV before taking it to hospital, make sure it is stored in a dry place where the temperature does not exceed 30°C.

For more information, see Section [5. What should I know while I am being given Epilim IV?](#) in the full CMI.

6. Are there any side effects?

All medicines have some unwanted side effects. Mostly these are mild and short-lived. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Epilim IV.

Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you have any thoughts of harming yourself or committing suicide. 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.

Epilim IV

Active ingredient: sodium valproate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Epilim IV. **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 Epilim IV.**

Where to find information in this leaflet:

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

1. Why am I being given Epilim IV?

Epilim IV contains the active ingredient sodium valproate. Epilim IV belongs to a group of medicines called anticonvulsants.

Epilim IV is used for the treatment of epilepsy in adults and children.

Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Epilim IV may also be used to control mania, a mental condition with episodes of overactivity, elation or irritability.

Epilim IV may be used alone or in combination with other medicines to treat your condition. Epilim IV may be used short-term in place of oral Epilim tablets or liquid when the medicine cannot be given by mouth.

Your doctor, however, may have prescribed Epilim IV for another reason.

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

There is no evidence that Epilim IV is addictive.

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

2. What should I know before I am given Epilim IV?

Warnings

You should not receive Epilim IV if:

- you are allergic to sodium valproate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have or have had any of the following medical conditions:
- liver disease (hepatic dysfunction) or severe hepatitis.
- a family history of hepatitis, especially when caused by medicines. Medicines used in the treatment of epilepsy,

including Epilim IV may have adverse effects on the liver and the kidneys

- a urea cycle disorder or a family history of urea cycle disorders.
- a family history of unexplained infant deaths.
- porphyria which is a rare blood disease of blood pigments.
- known ornithine transcarbamylase deficiency or a family history of ornithine transcarbamylase deficiency.
- known or suspected of having a genetic problem causing a mitochondrial disorder.
- you are pregnant, unless your doctor has determined no alternative treatment works for you.

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
- liver problems (hepatic insufficiency, hepatic damage)
- kidney problems
- urea cycle disorders
- ornithine transcarbamylase (OTC) deficiency
- an inborn deficiency in carnitine (a very rare metabolic disease) that is untreated, also called carnitine palmitoyltransferase (CPT) type II deficiency
- an inborn deficiency in carnitine and are taking carnitine
- have impaired dietary intake in carnitine, found in meat and dairy products, especially in children less than 10 years old
- systemic lupus erythematosus (SLE) (a disease affecting the skin, joints and kidneys)
- family history of a genetic problem causing mitochondrial disorder
- take any medicines for any other condition

If you have not told your doctor about any of the above, tell them before you take Epilim IV.

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

Pregnancy and breastfeeding

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

You must not use Epilim IV if you are pregnant, unless your doctor has determined that no alternative treatment works for you.

If you are a girl or woman of childbearing age, make sure that you talk to your doctor about the risks associated with taking Epilim IV during pregnancy.

You must not take Epilim IV unless you use an effective method of birth control (contraception) at all times during your treatment with Epilim IV. Do not stop taking Epilim IV or your contraception until you have discussed this with your doctor. Your doctor will advise you further.

If you are a parent or carer, tell your doctor when your child using Epilim IV experiences her first period.

Epilim IV can be harmful to unborn children when taken by a woman during pregnancy. It can cause serious birth defects and can affect physical and mental development of the child as it grows after birth. Also, children born to mothers who take Epilim IV throughout their pregnancy may be at risk of impaired cognitive development or withdrawal syndrome. However, do not stop taking Epilim IV unless your doctor says so as there are risks to the mother and child from uncontrolled epilepsy or uncontrolled mania episodes.

Your doctor may want to adapt your treatment and/or prescribe dietary supplements of folate.

Your doctor will discuss the risks and benefits of taking it if you are pregnant including when valproate is used in combination with other medicines to treat epilepsy.

What do I need to consider about contraception?

Use an effective method of contraception and consult your doctor before planning pregnancy.

Epilim IV can seriously harm an unborn child when taken during pregnancy. If you are a girl or woman of childbearing age, you must use at least one effective method of birth control (contraception) without interruption during your entire treatment with Epilim IV. Your doctor should discuss with you the most appropriate method of contraception for you.

Epilim IV should have little effect on the oral contraceptive pill, however, you should let your doctor know that you are taking it.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Medicines used in the treatment of epilepsy, including Epilim IV, pass into breast milk. Your doctor will discuss the risks and benefits of taking Epilim IV if you are breastfeeding or planning to breastfeed.

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 Epilim IV and affect how it works. These include:

- aspirin (and other salicylates)
- medicines used to prevent clots (anticoagulants) e.g. warfarin.
- other medicines used to treat epilepsy e.g. phenobarbital (phenobarbitone), methylphenobarbitone, primidone, phenytoin, carbamazepine, clonazepam, felbamate, lamotrigine, topiramate, diazepam, lorazepam, oxcarbamazepine, rifunamide and ethosuximide
- medicines used to treat depression e.g. monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- oral contraceptives. Epilim IV should have little effect on the oral contraceptive pill, however, you should let your doctor know that you are taking it.
- zidovudine or any other anti-viral medications
- cannabidiol (used to treat epilepsy and other conditions)
- antipsychotic medicines including clozapine (a medicine used to treat schizophrenia)

- quetiapine or olanzapine (medicines used to treat bipolar disorder and schizophrenia)
- mefloquine (a medicine used to treat malaria)
- propofol (a medicine used before and during general anaesthesia)
- nimodipine (a medicine used to help blood flow to the brain)
- cimetidine (used to treat stomach ulcers)
- erythromycin, rifampicin and carbapenem antibiotics such as Invanz and Merrem
- colestyramine (Questran Lite)
- acetazolamide (Diamox)
- metamizole (a medicine used to treat pain and fever)
- methotrexate (used to treat cancer and inflammatory diseases)
- some anti-infectives that contain pivalate (e.g., pivampicillin, adefovir dipivoxil)

These medicines and others may be affected by Epilim IV, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Tell your doctor or pharmacist if your child is taking any other medicines before they are given Epilim IV, for example, aspirin or any other drugs used to treat epilepsy.

Children, especially young children, can be more sensitive to some of the side effects of Epilim IV.

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

4. How am I given Epilim IV?

How it is given

Epilim IV will be given to you as an infusion or injection into the veins.

Adults:

If you are currently taking an oral formulation of Epilim (tablets, liquid or syrup) and are now changing over to Epilim IV, the total daily dose of Epilim IV should remain the same. In these circumstances, Epilim IV may be given as several separate injections, drips or infusions throughout the day, or as one long continuous drip or infusion lasting 24 hours a day.

If you are not currently taking Epilim or any other form of sodium valproate by mouth, your doctor will decide what dose you will receive, depending on your condition and other factors such as your weight.

Children:

The dose for children is usually 20 to 30mg for each kg of body weight every day. If epilepsy is not controlled the dose may be increased up to 40mg for each kg of body weight every day, as long as blood tests are done to check the amount of Epilim IV in the blood. If higher doses are needed, further blood tests must be done to check that Epilim IV is not causing side effects.

If you take too much Epilim IV

Your doctor will decide what dose of Epilim IV you need, and this will be given under close supervision, usually in a hospital setting.

The risk of an overdose in these circumstances is low. In the event of an overdose occurring, your doctor will decide on the treatment necessary.

If you have been given too much Epilim IV, you may experience:

- reduction in consciousness possibly leading into coma
- shortness of breath
- muscle weakness
- shrinking of the pupil in the eye
- too much acid in the body, causing fast breathing, confusion, tiredness, headache, yellowing of the skin (jaundice) and increased heart rate
- dizziness, lightheadedness
- collapse due to very low blood pressure
- convulsions
- severe headache, blurred vision, blind spot or vision loss
- tiredness, confusion, excessive thirst
- death

5. What should I know while I am being given Epilim IV?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using Epilim IV.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.
- Call your doctor or nurse straight away if you do not feel well while Epilim IV is being given to you.

All mentions of suicide or violence must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Epilim IV affects you.

Epilim IV may cause drowsiness or light-headedness in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy or light-headed.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you have more than 2 drinks per day, you may be putting yourself at risk of a seizure, or fit.

The effects of alcohol could be made worse while you are receiving Epilim IV.

Combining Epilim IV and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while you are being treated with Epilim IV.

Looking after your medicine

- If you need to store Epilim IV before taking it to hospital, make sure it is stored in a dry place where the temperature does not exceed 30°C..

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on a windowsill.

Heat and damp can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use 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
<p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • nausea or vomiting • abdominal cramps or pain • changes in appetite • changes in your weight • diarrhoea <p>Mouth related:</p> <ul style="list-style-type: none"> • bleeding, tender or enlarged gums <p>Head and neurology related:</p> <ul style="list-style-type: none"> • headache • unusual movements, including tremor and shaking • rapid uncontrollable movements of the eye or double vision • unsteadiness when walking, dizziness or light-headedness • depression • feeling tired or drowsy • memory impairment • confusion • hallucinations • disturbance in attention • changes in behaviour including aggression and agitation <p>Hormone related:</p> <ul style="list-style-type: none"> • irregular menstrual periods <p>Other side effects:</p> <ul style="list-style-type: none"> • hair loss • nail and nail bed disorders • loss of bladder control • decrease in carnitine levels (shown in blood or muscular tests) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These are the more common side effects of Epilim IV. Mostly these are mild and short-lived.</p>

Serious side effects

Serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none"> severe upper stomach pain, often with nausea and vomiting <p>Blood related:</p> <ul style="list-style-type: none"> blood clotting problems spontaneous bruising or bleeding signs of decreased white blood cells or bone marrow problems such as fever and breathing difficulty signs of increased ammonia in the blood such as problems with balance and co-ordination, feeling lethargic or less alert, vomiting <p>Head and neurology related:</p> <ul style="list-style-type: none"> more frequent or more severe seizures (fits) fainting bizarre behaviour suicidal thoughts suicide attempts <p>Liver related:</p> <ul style="list-style-type: none"> signs of liver and pancreas problems such as vomiting, loss of appetite, generally feeling unwell, tiredness, yellowing of the skin and/or eyes, dark urine or blood in urine, pain in the abdomen <p>Other side effects:</p> <ul style="list-style-type: none"> rashes joint pain passing a lot of urine and feeling thirsty (Fanconi syndrome) swelling of the feet and legs, weight increase due to fluid build up 	<p>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 or if you have any thoughts of harming yourself or committing suicide.</p> <p>You may need urgent medical attention or hospitalisation.</p>

Serious side effects	What to do
<p>Additional side effects in children</p> <ul style="list-style-type: none"> signs of liver damage or inflammation of the pancreas (pancreatitis). Signs may include repeated vomiting, extreme tiredness, loss of appetite, severe upper stomach pain, nausea, jaundice (yellowing of the skin or whites of the eyes), swelling of the legs or worsening of your epilepsy or a general feeling of being unwell aggression agitation disturbance in attention abnormal behaviour hyperactivity 	<p>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.</p> <p>Your child may need urgent medical attention or hospitalisation.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> learning disorder <p>Some side effects of valproate occur more frequently in children or are more severe compared to adults.</p>	

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 as follows:
Australia: Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

New Zealand: <https://nzphvc.otago.ac.nz/reporting/>

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 Epilim IV contains

Active ingredient (main ingredient)	Each vial contains the active ingredient sodium valproate 400mg.
Other ingredients (inactive ingredients)	Water for injections
Potential allergens	None

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

What Epilim IV looks like

Epilim IV comes as a white powder in a glass vial.

Each box of Epilim IV contains one glass vial and one ampoule of solvent (water for injections). (AUST R 104416)

Who distributes Epilim IV

Distributed in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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