

Epilim[®] IV

Sodium Valproate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Epilim IV.

It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of using Epilim IV against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Epilim IV is used for

Epilim IV is a medicine 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.

Epilim IV belongs to a group of medicines called anticonvulsants.

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.

Before you are given it

When you must not receive it

You should not receive Epilim IV if 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.

If you are girl or woman of childbearing age you must not be given 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 (see 'Before you start to take it').

You should not be given Epilim IV if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Before you are given it

Tell your doctor if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes

If you are a female patient of child-bearing age, make sure that you talk to your doctor about the risks associated with taking Epilim IV during pregnancy.

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

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

Epilim IV can be harmful to unborn children when taken by a woman during pregnancy. It can cause serious birth defects and can affect the way in which the child develops as it grows.

Also, children born to mothers who take Epilim IV throughout their pregnancy may be at risk of impaired cognitive development or withdrawal syndrome.

Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Tell your doctor if you are breastfeeding or planning 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 it if you are breastfeeding or planning to breastfeed.

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.

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

- liver problems (hepatic insufficiency, hepatic damage)
- kidney problems
- urea cycle disorders
- ornithine transcarbamylase (OTC) deficiency
- carnitine palmitoyltransferase (CPT) type II deficiency

- systemic lupus erythematosus (a disease affecting the skin, joints and kidneys)
- family history of a genetic problem causing mitochondrial disorder.

Tell your doctor if you plan to have surgery.

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

Taking other medicines

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

Some medicines and Epilim IV may interfere with each other. 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
- 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)

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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being 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 (overdose)

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

While you are receiving it

Things to be careful of

Be careful when driving or operating machinery until you know how Epilim IV affects you.

It may cause drowsiness in some people. Make sure you know how you react to Epilim IV before you drive a car, operate

machinery or do anything else that could be dangerous if you are drowsy or light headed.

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

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

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or nurse as soon as possible if you do not feel well while Epilim IV is being given to you.

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

- nausea or vomiting
- bleeding, tender or enlarged gums
- abdominal cramps or pain

- changes in appetite
- changes in your weight
- irregular menstrual periods
- diarrhoea
- loss of bladder control
- headache
- unusual movements, including tremor and shaking
- rapid uncontrollable movements of the eye or double vision
- unsteadiness when walking, dizziness or light-headedness
- depression
- hair loss
- feeling tired or drowsy
- memory impairment
- confusion
- hallucinations
- disturbance in attention
- changes in behaviour including aggression and agitation

- nail and nail bed disorders

These are the more common side effects of Epilim IV. Mostly these are mild and short-lived.

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.

Tell your doctor immediately if you notice any of the following:

- more frequent or more severe seizures (fits)
- blood clotting problems
- spontaneous bruising or bleeding
- skin rashes
- signs of liver 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
- swelling of the feet and legs, weight increase due to fluid build up
- fainting
- bizarre behaviour
- suicidal thoughts

- suicide attempts
- severe upper stomach pain, often with nausea, vomiting and/or loss of appetite especially when prolonged

These are serious side effects. You may need urgent medical attention.

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

Other side effects not listed above may also happen in some patients. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Ask your doctor to answer any questions you may have.

After receiving it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

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.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking Epilim IV, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it 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).

Ingredients

Each vial contains the active ingredient sodium valproate 400mg.

Manufacturer/Sponsor

Epilim IV is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

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