What is Epilim®

Sodium Valproate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Epilim.

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 your taking Epilim against the benefits they expect it will have for you.

Please read this leaflet very carefully before you start to take your Epilim, even if you have taken Epilim before.

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 is used for

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

Epilim may be used alone or in combination with other medicines to treat your condition.

Your doctor, however, may have prescribed Epilim 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 is addictive.

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

Do not take Epilim 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.

Do not take it after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor or pharmacist 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 during pregnancy.

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

Like most medicines of this kind, Epilim may affect your developing baby if taken in the first trimester of pregnancy, as it is suspected of causing an increased risk of malformations in the exposed foetus. Also, children born to mothers who take Epilim throughout their pregnancy may be at risk of impaired cognitive development or withdrawal.
syndrome. However, do not stop taking Epilim 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.

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

Medicines used in the treatment of epilepsy, including Epilim, 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 take Epilim.

**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 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. phenobarbitone, methylphenobarbitone, primidone, phenytoin, carbamazepine, clonazepam, felbamate, lamotrigine, topiramate, diazepam, lorazepam, oxcarmazepine, 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 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 antiviral medications
- neuroleptic agents 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.
- cholestryramine (Questran Lite)
- acetazolamide (Diamox)

These medicines and others may be affected by Epilim, 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 you start giving them Epilim, 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Epilim.

**How to take it**

**How much to take**

Your doctor will tell you how much to take, and in what form (liquids or tablets) you should take it. This may depend on your age, your condition and whether or not you are taking any other medicines.

Your doctor may recommend that you start with a low dose of Epilim and slowly increase the dose to the lowest amount needed to control your condition.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Epilim may not work as well.

**How to take it**

Epilim Tablets (white tablets)

Epilim tablets may be taken twice a day.

Swallow the tablets whole with a full glass of water or other liquid or take them with food.
The tablets may be crushed and taken with food or drinks.

Do not take them with "fizzy" water, soda or soft drinks.

Epilim EC Tablets (lilac tablets)
Swallow the lilac tablets (EC200 and EC500) whole with a glass of water or other liquid.

Do not crush or chew the tablets. The lilac tablets have a special coating to stop them dissolving until they have gone through the stomach and into the intestines. If you chew them, the coating is destroyed.

Epilim Syrup and Liquid
Epilim Syrup and Sugar-Free Liquid should be taken 2-3 times a day.

Shake the bottle well and accurately pour the dose into a medicine measure before taking it. Shaking the bottle and using a medicine measure will make sure you get the correct dose. You can get a medicine measure from your pharmacist.

When to take it
Your doctor will advise you when to take Epilim.
Always follow your doctor's instructions.

Take Epilim at about the same time each day. Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

If you are not sure when to take it, ask your doctor.

How long to take it
Continue taking your medicine for as long as your doctor tells you.

Epilim helps control your condition but does not cure it. Therefore you must take it every day.

If you forget to take it
Always remember to take your prescribed dose otherwise you may find that either your seizures or manic symptoms may return.

If you forget a dose, take your next dose as usual. Do not take a double dose to make up for the dose that you missed. This may increase the chance of your getting unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)
Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Epilim.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Epilim you may feel dizzy, drowsy or have cramps in the abdomen.

While you are taking it

Things you must do
Tell all the doctors, dentists and pharmacists who are treating you that you are taking Epilim.

If you are about to be started on any new medicine, tell your doctor that you are taking Epilim.

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.

Be sure to keep all of your doctors' 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 prevent unwanted side effects.

Things you must not do
Do not take more than the recommended dose unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Epilim, or lower the dosage, without checking with your doctor.

Things to be careful of

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

It may cause drowsiness or light-headedness in some people, especially at the beginning of treatment. 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.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.

Epilim may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

Diabetics are advised that Epilim Syrup contains 3.6 g/5 mL of sucrose (sugar).

The effects of alcohol could be made worse while taking Epilim. Combining it and alcohol can make you more sleepy, dizzy or light headed. Your doctor may suggest you avoid alcohol while you are treated with Epilim.

What do I need to consider about contraception?

Unplanned pregnancy may not be desirable in patients receiving medicines for epilepsy or mania. You should use an effective method...
of contraception and consult your 
doctor before planning pregnancy; 
for example, your doctor may want 
you to start taking folate tablets.

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

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 pharmacist as 
soon as possible if you do not feel 
well while you are taking Epilim.

Tell your doctor or pharmacist 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
- headache
- unusual movements, including 
tremor and shaking
- rapid uncontrollable movements 
of the eye
- 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 
agression and agitation
- nail and nail bed disorders

These are the more common side 
effects of Epilim. 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, or 
go to Accident and Emergency at 
your nearest hospital if you notice 
any of the following:

- more frequent or more severe 
seizures (fits)
- blood clotting problems
- spontaneous bruising or 
bleeding
- 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 and vomiting

These are very 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 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 taking 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

Keep your tablets in the blister 
pack until it is time to take them. 
If you take the tablets out of the box 
or the blister pack they may not 
keep well.

Keep Epilim and Epilim EC 
tablets in a cool dry place where 
the temperature stays below 
30°C.

Keep Epilim Syrup and Liquid in 
a cool dry place where the 
temperature stays below 25°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 the ground is a 
good place to store medicines.

Dispersion

If your doctor tells you to stop 
taking Epilim, 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 100 mg Crushable tablets - 
White, round, scored tablets.

Epilim EC200 - Lilac, round, 
enteric-coated tablets.

Epilim EC500 - Lilac, round, 
enteric-coated tablets.
Epilim Syrup - Red, cherry flavoured syrup.

Epilim Liquid Sugar Free - Red, cherry flavoured liquid.

The tablets are available in boxes of 100 tablets.

Epilim Syrup and Liquid are available in 300 mL bottles.

**Ingredients**

**Active Ingredient:**
- Epilim 100 mg Crushable tablets - 100 mg sodium valproate
- Epilim EC200 - 200 mg sodium valproate
- Epilim EC500 - 500 mg sodium valproate
- Epilim Syrup - 200 mg/5 mL sodium valproate
- Epilim Liquid Sugar Free - 200 mg/5 mL sodium valproate

**Inactive Ingredients:**
- Epilim 100 mg Crushable tablets - Maize starch, silicon dioxide, kaolin, magnesium stearate
- Epilim EC200 - Povidone, purified talc, magnesium stearate, calcium silicate, citric acid monohydrate, macrogol 6000, hypromellose, polyvinyl acetate phthalate, hyprollose, diethyl phthalate, stearic acid, amaranth aluminium lake, indigo carmine aluminium lake, titanium dioxide
- Epilim EC500 - Povidone, purified talc, magnesium stearate, calcium silicate, citric acid monohydrate, macrogol 6000, hypromellose, polyvinyl acetate phthalate, hyprollose, diethyl phthalate, stearic acid, amaranth aluminium lake, indigo carmine aluminium lake, titanium dioxide
- Epilim Syrup - Sucrose, sorbitol, saccharin sodium, sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate, brilliant scarlet 4R, imitation cherry flavour, purified water.
- Epilim Liquid Sugar Free - Sorbitol, saccharin sodium, citric acid, hyetellose, sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate, brilliant scarlet 4R, imitation cherry flavour, purified water.

**Manufacturer/Sponsor**

Epilim is supplied in Australia by:

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

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- Epilim 100 mg Crushable tablets - AUST R 15373
- Epilim EC200 - AUST R 15369
- Epilim EC500 - AUST R 15370
- Epilim Syrup - AUST R 15372
- Epilim Liquid Sugar Free - AUST R 74711

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