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 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 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.

Before you take it

When you must not take it

Do not take it 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 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 a girl or woman of childbearing age, you must not take Epilim unless you use an effective method of birth control (contraception) at all times during your treatment with Epilim. Do not stop taking Epilim or your contraception until you have discussed this with your doctor. Your doctor will advise you further (see 'Before you start to take it').

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.

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

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

Epilim 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 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. 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 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
- colestyramine (Questran Lite)
- acetazolamide (Diamox)
- Metamizole (a medicine used to treat pain and fever)

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 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 lightheaded. Your doctor may suggest you avoid alcohol while you are treated with Epilim.

What do I need to consider about contraception?

Epilim 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. Your doctor should discuss with you the most appropriate method of contraception for you.

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
- 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. 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.

Keep your tablets in the pack until it is time to take them,

Disposal

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, hyprolose, 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, hyprolose, 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 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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