Epilim®

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 using Epilim?

Epilim contains the active ingredient sodium valproate. Epilim is used to treat epilepsy in adults and children and mania in adults.

For more information, see Section 1. Why am I using Epilim? in the full CMI.

2. What should I know before I use Epilim?

Do not use if you have ever had an allergic reaction to Epilim or any of the ingredients listed at the end of the CMI.

Epilim can seriously harm an unborn child when taken during pregnancy. If you are a female able to have a baby, you must use an effective method of birth control (contraception) during your entire treatment with Epilim. Schedule an urgent appointment with your doctor if you want to become pregnant or if you think you became pregnant. Do not stop taking Epilim unless your doctor tells you to, as it may be dangerous for you.

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 use Epilim? in the full CMI and read the patient guide available electronically through QR code on the carton (www.sanofi.com.au/valproate).

3. What if I am taking other medicines?

Some medicines may interfere with Epilim 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 do I use Epilim?

- Your doctor will tell you how much to take. This may depend on your age, your condition and whether or not you are taking any other medicines.

More instructions can be found in Section 4. How do I use Epilim? in the full CMI.

5. What should I know while using Epilim?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Epilim. • Plan annual appointments with your specialist. • If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine. • Ensure you use effective contraception and if you become pregnant while you are taking this medicine, tell your doctor immediately
Things you should not do	• If you suffer from mania, do not use Epilim if you are pregnant. • If you suffer from epilepsy , do not use Epilim if you are pregnant, unless your doctor has determined that no other treatment works for you • Do not stop using this medicine suddenly or lower the dosage, without checking with your doctor as your condition may become worse. • Do not take more than the recommended dose unless your doctor tells you to.
Driving or using machines	• Epilim may cause drowsiness, light-headedness dizziness or sleepiness, • Make sure you know how you react to it before you drive a car, operate machinery or perform any activity that requires alertness. • 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	• Avoid alcohol while you are being treated with Epilim. • Combining Epilim and alcohol can make you more sleepy, dizzy or lightheaded.

Looking after your medicine	• Store tablets in cool dry place below 30℃.Keep tablets in blister pack. • Store syrup or liquid in cool dry place below 25℃.

For more information, see Section 5. What should I know while using Epilim? 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.

Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital :

- If you or your child develops a sudden illness and particularly if it includes repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness, loss of appetite, 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
- If you or your child taking Epilim develops problems with balance and co-ordination, feeling lethargic or less alert, vomiting,
- If seizures become worse or happen more frequently
- If you have any thoughts of harming yourself or committing suicide
- If you think you are pregnant

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®

Active ingredient: *sodium valproate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Epilim. Read the entire leaflet carefully before you start taking this medicine. **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.**

Where to find information in this leaflet:

1. Why am I using Epilim?
2. What should I know before I use Epilim?
3. What if I am taking other medicines?
4. How do I use Epilim?
5. What should I know while using Epilim?
6. Are there any side effects?
7. Product details

1. Why am I using Epilim?

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

Epilim is used to treat 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 may also be used to control mania, a mental condition with episodes of overactivity, elation or irritability. Epilim should not be used in children and adolescents under 18 years of age for the treatment of mania. 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.

Epilim has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms seem to be the same as yours.

There is no evidence that Epilim is addictive.

2. What should I know before I use Epilim?

Warnings

Do not use Epilim:

- **if you are pregnant, unless your doctor has determined that no other treatment works for you**
- **unless you use an effective method of birth control (contraception) at all times during your treatment with Epilim**
- 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 severe 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.
    - hepatic 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 for example Alpers-Huttenlocher syndrome.
    - inborn deficiency in carnitine, a very rare metabolic disorder that is untreated.
    - you are pregnant, unless your doctor has determined no alternative treatment works for you.

Check with your doctor if you:

- have any other medical conditions, especially the following:
    - liver problems (hepatic insufficiency, hepatic damage)
    - impaired kidney function as your doctor may want to monitor the valproate level or adjust your dose
    - urea cycle disorders because of a risk of increased ammonia level in the blood
    - 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 because you are at increased risk of muscle disorders
    - 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 because of a risk of damage to your liver
    - put on weight as your appetite may be increased
- take any medicines for any other condition

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 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 during pregnancy. Your doctor will explain what might happen to your baby if you become pregnant whilst taking Epilim.

You must not take Epilim unless you use an effective method of birth control (contraception) at all times during your treatment with Epilim. If you decide later you want to have a baby, you must not stop taking Epilim or your contraception until you have discussed this with your doctor. Your doctor will advise you further on alternative treatment options. Your doctor may decide to change the dose of Epilim or switch you to another medicine or stop treatment with Epilim several months before you become pregnant.

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

Epilim can be harmful to unborn children when taken by a woman during pregnancy. It can cause serious birth defects that require medical treatment and can affect physical and mental development of the child as it grows after birth. Babies are also at risk of lower weight than expected for their age at birth. The most frequently reported birth defects include spina bifida (where the bones of the spine are not properly developed), facial and skull malformations, heart, kidney, urinary and sexual organ malformations, limb defects, and multiple associated malformations affecting several organs and parts of the body.

Birth defects may result in disabilities which may be severe. As valproate has been used for many years, it is known that in women who take valproate during pregnancy around 11 babies in every 100 will have birth defects. This compares to 2 to 3 babies in every 100 born to women from the general population. It is estimated that up to 30-40% of children whose mothers took valproate during pregnancy may have problems with early childhood development. Children affected can be slow to walk and talk, be intellectually less able than other children, and have difficulties with language and memory.

Hearing problems or deafness as well as eye malformations in association with other congenital malformations which may affect vision, have been reported in children exposed to valproate during pregnancy.

Autistic spectrum disorders are more often diagnosed in children exposed to valproate during pregnancy and there is some evidence that children exposed to valproate during pregnancy are at increased risk of developing Attention Deficit Hyperactivity Disorder (ADHD).

If you take valproate during pregnancy, your baby may have a lower weight than expected for their age at birth.

There may also be blood clotting problems, hypoglycemia and hypothyroidism in the newborn children of mothers who have taken Epilim during pregnancy.

Children born to mothers who take Epilim throughout their pregnancy may be at risk of impaired cognitive development or withdrawal syndrome (agitation, irritability, hyperexcitability, jitteriness, hyperkinesia, tonicity disorders, tremor, convulsions and feeding problems) if Epilim is taken during the last trimester of pregnancy. 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 when trying for a baby. Folic acid can lower the general risk of spina bifida and early miscarriage that exists with all pregnancies. However it is unlikely that it will reduce the risk of birth defects associated with valproate use.

In exceptional circumstances when Epilim is the only available treatment option during pregnancy, you will be monitored very closely both for the management of your underlying condition and to check how your unborn child is developing. You and your partner should receive counselling and support regarding the valproate exposed pregnancy.

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. The higher the dose, the higher the risks but all doses carry a risk.

Potential risk to children of fathers taking valproate in the 3 months prior to conception

A study suggests that if you take valproate in the 3 months prior to conception, your child may have a higher risk for impaired mental and/or motor development compared to children born to fathers who used lamotrigine or levetiracetam, other medicines that can be used to treat your disease. In this study, around 5 children in 100 had such disorders when born from fathers treated with valproate, and around 3 children in 100 when born from fathers treated with the other medicines. There are no data on this potential risk to children fathered more than 3 months after stopping valproate treatment (the time needed for new sperm to be formed).

As a precautionary measure, your doctor will discuss with you

- The potential risk when fathering a child if you are treated with valproate,
- The need to use effective contraception (birth control) for you and your female partner during the treatment and for 3 months after stopping valproate
- The need to consult your doctor to discuss alternative treatment options, as soon as you are planning to father a child and before discontinuing contraception (birth control),

- To not donate sperm during treatment and for 3 months after stopping treatment.

Do not stop your treatment without talking to your doctor. If you stop your treatment, your symptoms may become worse. If your female partner becomes pregnant while you used valproate in the 3 months prior to conception, both of you should contact the doctor for counseling.

You should get regular (at least annual) appointments with your doctor. During this visit your doctor will make sure you understand the risk and precautions associated with valproate use.

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

Contraception use

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

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. Some birth control pills (oestrogen containing birth control pills) may lower valproate levels in your blood. 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.

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 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)
- oestrogen containing products or 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 anti-viral medications
- cannabidiol (used to treat epilepsy and other conditions)
- 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. The combination of Epilim and carbapenems should be avoided because it may decrease the effect of Epilim.
- rufinamide
- colestyramine (Questran Lite)
- acetazolamide (Diamox)
- protease inhibitors such as lopinavir and ritonavir (used to treat HIV)
- 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, or worsen adverse reactions, 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.

If your child is under 3 years of age, Epilim should not be administered together with aspirin. Epilim can affect the liver and rarely the pancreas in a very small number of patients. The risk of liver damage is increased if Epilim is taken by your child under 3 years who is taking other antiepileptic medicine at the same time or has other neurological or metabolic disease and severe form of epilepsy.

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

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.

4. How do I use Epilim?

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 provided and use Epilim until your doctor tells you to stop.
- If you take the wrong dose, Epilim may not work as well.
- Make sure you keep your regular check up appointments. They are very important, as your dosage may need to be changed.

When to take Epilim

- Epilim should be taken at about the same time each day.
- Taking your tablets at the same time each day will have the best effect. It will help you remember when to take the tablets.
- 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.

How to take Epilim

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 If you crush or 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.
- Epilim Liquid is supplied with a 20 mL marked measuring cup.

Cup Mark	Corresponding Epilim Liquid Dose
2.5 mL 5 mL 10 mL 15 mL 20 mL	100 mg 200 mg 400 mg 600 mg 800 mg

- You can get a medicine measure from your pharmacist for Epilim Syrup.
- If the dose is less than 100 mg (2.5mL), talk to your doctor or pharmacist about how to measure the dose of Epilim Syrup and Liquid.

If you forget to use Epilim

Epilim should be used regularly at the same time each day. If you miss your dose at the usual time, take your next dose as usual. Contact your doctor if you miss several doses.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting unwanted side effects.

- Always remember to take your prescribed dose otherwise you may find that either your seizures or manic symptoms may return.
- 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 some hints.

If you use too much Epilim

If you think that you have used too much Epilim, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia**), or (**by calling 0800 764 766 in New Zealand**) 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.

If you take too much Epilim, 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 may become worse or happen more frequently
- severe headache, blurred vision, blind spot or vision loss
- tiredness, confusion, excessive thirst
- death

5. What should I know while using Epilim?

Things you should do

- **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.**
- **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.**

Call your doctor straight away if you:

- If you become pregnant while you are taking this medicine
- If you or your child develops an allergic reaction, especially with effects on skin and mucosa, and/or fever

Remind any doctor, dentist or pharmacist you visit that you are using Epilim.

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.

Things you should not do

- 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.
- 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.

Driving or using machines

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

Epilim may cause drowsiness or light-headedness in some people, especially at the beginning of treatment or in combination with other antiepileptic medicines or benzodiazepines. 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).

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 taking Epilim.

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

Looking after your medicine

- 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.

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 window sills.

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 (EXP) printed on the pack. If you take this medicine after the expiry date has passed, it may not work as well.

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

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
Gastrointestinal related: • nausea or vomiting • abdominal cramps or pain • changes in appetite • changes in your weight • diarrhoea **Mouth related:** • bleeding, tender or enlarged gums	**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
• sore, swollen mouth, mouth ulcers and burning feeling of mouth **Head and neurology related:** • headache • unusual movements, including tremor and shaking • rapid uncontrollable movements of the eye or double vision • unsteadiness when walking, dizziness or light-headedness • tingling or numbness of the hands and feet • hearing problems or deafness • depression • feeling tired or drowsy • memory impairment • confusion • hallucinations • disturbance in attention • changes in behaviour including aggression and agitation • learning disorder **Hormone related:** • irregular menstrual periods • acne • male infertility **Respiratory related:** • Pneumonia **Other side effects:** • hair loss • nail and nail bed disorders • loss of bladder control • decrease in carnitine levels (shown in blood or muscular tests) • reduced levels of vitamin B8 • bedwetting • excessive hairiness • decrease in body temperature • inflammation of small blood vessels • bone disorders and fractures • darker areas of skin and mucous membranes (hyperpigmentation)	

Serious side effects

Serious side effects	What to do
Gastrointestinal related: • severe upper stomach pain, often with nausea and vomiting	**Call your doctor straight away, or go straight to the**
Blood related: • 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 **Head and neurology related:** • more frequent or more severe seizures (fits) • fainting • drowsiness, change in conscious level (including coma), confusion, sluggishness or abnormal behaviour and memory loss with or without more frequent or severe fits particularly if phenobarbital and topiramate are taken at the same time or if the dose of Epilim has been suddenly increased • bizarre behaviour • suicidal thoughts • suicide attempts **Liver related:** • 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 **Other side effects:** • rashes or skin lesions with a pink/red ring and a pale center which may be itchy, scaly of filled with fluid, especially on the palms or soles of your feet • blisters with skin peeling or bleeding with sometimes flu-like symptoms such as fever, chills or aching muscle • joint pain • passing a lot of urine and feeling thirsty (Fanconi syndrome) • swelling due to an allergy with painful itchy welts often around the eyes, lips, throat and sometimes hands and feet	**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.** **You may need urgent medical attention or hospitalisation.**

Serious side effects	What to do
• swelling of the feet and legs, weight increase due to fluid build up • syndrome with skin rash, fever, lymph node enlargement and possible impairment of other organs. These may be signs of a condition called DRESS (Drug Rash with Eosinophilia and Systemic Symptoms) • underactive thyroid gland which may cause tiredness or weight gain • kidney disease resulting in reduced urinary output	

Serious side effects	What to do
Additional side effects in children • 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 • learning disorder Some side effects of valproate occur more frequently in children or are more severe compared to adults.	**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.** **Your child may need urgent medical attention or hospitalisation.**

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

If you get any side effects, talk to your doctor or pharmacist immediately. 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.

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 Epilim contains

Active ingredient **(main 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
Other ingredients **(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 (colourless to slightly yellow) - Sucrose, sorbitol, saccharin sodium, imitation cherry flavour, citric acid, 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
Potential allergens	-

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

What Epilim 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 - Colourless to slightly yellow, 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.

(Epilim 100 mg Crushable tablets - AUST R 15373)

(Epilim EC200 - AUST R 15369)

(Epilim EC500 - AUST R 15370)

(Epilim Syrup - AUST R 525786)

(Epilim Liquid Sugar Free - AUST R 74711)

Who distributes Epilim

Distributed by:

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Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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