

# EPILIM<sup>®</sup> SYRUP

Sodium Valproate (200mg/5ml)

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## What Epilim is used for

Epilim is used for the treatment of generalised (affects the entire brain) or partial (only affects a small part of the brain) epilepsy (fits) with the following pattern of seizures:

- absence (a short period of "blinking out")
- myoclonic (brief, shock-like jerks of muscles)
- tonic-clonic (muscles stiffen, and jerking movements)
- atonic (muscles suddenly lose strength)
- mixed
- simple (awareness is retained) or complex (impairment of awareness) seizures
- secondary generalised seizures (spread to both sides of the brain after the initial event)
- specific syndromes (Wes, Lennox-Gastaut)

Epilim may also be used to control bipolar disorder, a mental condition with mania symptoms (an elevation of mood).

## How Epilim works

Epilim contains a medicine called sodium valproate. This belongs to a group of medicines called anti-convulsants or anti-epileptic agents. It works by controlling brain chemicals which send signals to nerves so that seizures do not happen.

## Before you use Epilim

### When you must not use it

Do not take Epilim if:

- You are allergic (hypersensitive) to sodium valproate or any of the other ingredients of Epilim. (listed in Section 8 below).
- You have liver problems or you or your family have a history of liver problems
- You have a rare illness called porphyria (a group of disorders where there is a problem with the production of haem within the body. Haem is used to make haemoglobin in red blood cells).
- You have mitochondrial disorders (eg. Alpers-Huttenlocher Syndrome)

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Epilim.

### Before you start to use it

A small number of people being treated with Epilim have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

## Check with your doctor before taking this medicine if:

- You have diabetes. This medicine may affect the results of urine tests
- You have kidney problems.
- You have a 'urea cycle disorder' where too much ammonia builds up in the body.
- You have an illness called "systemic lupus erythematosus (SLE)" - a disease of the immune system which affects skin, bones, joints and internal organs
- You are pregnant or you are a woman of child-bearing age
- You are taking carbapenem agents.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Epilim.

## Taking Epilim with drink

Alcohol intake is not recommended during treatment.

## Weight gain

Taking Epilim may make you put on weight.

## Blood tests

Your doctor may wish to do blood tests before you start taking Epilim and during your treatment.

### Taking other medicines

## The following medicines can increase the chance of you getting side effects, when taken with Epilim:

- Some medicines used for pain and inflammation such as aspirin.
- Some other medicines used to treat fits (epilepsy) such as phenobarbital, primidone, phenytoin, carbamazepine, topiramate, lamotrigine and felbamate.

## Epilim may increase the effect of the following medicines:

- Medicines used for thinning the blood (such as warfarin)
- Zidovudine used to treat HIV infection
- Temozolomide used to treat cancer
- Medicines for depression
- Monoamine oxidase inhibitors (MAOI) such as moclobemide, selegiline, linezolid
- Medicines used to calm emotional and mental conditions such as diazepam

## The following medicines can affect the way Epilim works:

- Some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine
- Cimetidine used for stomach ulcers
- Some medicines used for infections (antibiotics) such as rifampicin and erythromycin
- Carbapenem agents (antibiotics used to treat bacterial infections) such as imipenem, meropenem and panipenem. The combination of

Epilim and Carbapenem agents should be avoided because it may decrease the effect of your medicine.

- Colestyramine used to lower blood fat (cholesterol) levels.

### How to use Epilim

Always take Epilim exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Your doctor will decide how much Epilim to give you or your child depending on you or your child's body weight.
- Take this medicine by mouth
- Take Epilim with or after food. This will help to stop the feelings of sickness that may happen after taking Epilim
- Do not mix Epilim with any other liquids. If it is necessary to dilute Epilim syrup, the recommended diluent is Syrup BP without SO<sup>2</sup> as preservative. Diluted product will have 14-day shelf life.
- Epilim can be taken twice daily.

### How much to use

#### Adults (including the elderly)

- The starting dose is 600mg daily. Your doctor should gradually increase this dose by 200mg every 3 days depending on your condition
- The usual dose is between 1000mg and 2000mg (20-30mg per kilogram of body weight) each day
- This may be increased each day to 2500mg depending on your illness.

#### Children over 20 kilograms

- The starting dose should be 400mg daily. Your doctor should increase this dose depending on your child's illness
- The usual dose is then between 20mg and 30mg for each kilogram of body weight each day
- This may be further increased to 35mg for each kilogram of body weight each day depending on your child's illness.

#### Children under 20 kilograms

- The usual dose is 20mg for each kilogram of body weight each day
- Depending on the child's condition your child's doctor may decide to increase this dose which above 40mg/kg/day will require monitoring.

### If you have kidney problems

- Your doctor may decide to adjust your or your child's dose

### If you are taking other medicines for 'fits' (epilepsy)

- You or your child may be taking other medicines for epilepsy at the same time as Epilim. If so, your doctor should gradually initiate treatment depending on you or your child's condition
- Your doctor may increase the dose of Epilim by 5 to 10mg for each kilogram of body weight each day depending on which other medicines you are taking.

### Adults with mania associated with bipolar disorders

- The starting dose is 1000mg daily. Your doctor should increase your dose rapidly to achieve the desired effects.
- The usual dose is then between 1000mg and 2000mg each day.
- This may be increased to not more than 3000mg each day depending on your illness.

### When to use it

**Take Epilim at about the same time each day unless your doctor tells you otherwise.**

### How long to use it

Keep taking until your doctor tells you to stop. Do not stop taking Epilim just because you feel better. **If you stop your fits may come back.**

### If you forget to use it

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

### If you use too much (overdose)

If you take more Epilim than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. The following effects may happen: feeling sick or being sick, pupils of the eye become smaller, dizziness, weak muscles and poor reflexes, breathing problems, and fits (seizures).

### While you are using it

#### Things you must do

#### **Tell your doctor immediately if you are pregnant or breast-feeding**

You should not take Epilim if you are pregnant or a woman of child-bearing age unless explicitly advised by your doctor.

- Unplanned pregnancy is not desirable
- You should use an effective method of contraception.

Women taking Epilim during pregnancy have a higher risk of having a child with an abnormality. These abnormalities include:

- Head and face deformities including cleft palate (a gap or depression in the lip)
- Malformations of the arms and legs
- Deformities of the tube from the bladder to the penis, where the opening is formed in a different place
- Heart and blood vessel malformations, including heart defects
- An abnormality of the spinal cord called 'Spina bifida'
- Malformations of the urethra

#### **Taking folic acid 5mg each day**

as soon as you stop contraception may lower the risk of having a baby with spina bifida. These other defects can usually be detected with specialized prenatal monitoring.

Pregnant mothers who take Epilim may have babies with:

- Blood clotting problems
- Hypoglycaemia (low blood sugar)
- Hypothyroidism (underactive thyroid gland)
- Withdrawal syndrome (such as, in particular agitation, irritability, hyper-excitability, jitteriness, hyperkinesia, tonic disorders, tremor, convulsions and feeding disorders) if valproate is taken during the last trimester of pregnancy.

Some babies born to mothers who took Epilim during pregnancy may develop less quickly than normal or have autistic disorders.

#### **Breast-feeding**

Very little Epilim gets into the breast milk. Talk to your doctor before breast-feed your baby.

Things you must not do

- 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 change the dosage, without checking with your doctor.

Things to be careful of

**Driving and using machines**

You may feel sleepy when taking Epilim. **If this happens to you, do not drive or use any tools or machines.** Taking with other antiepileptic medicines may increase sleepiness.

**Side Effect**

Like all medicines, Epilim can cause side effects, although not everyone gets them.

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

You may not experience any of them.

**Tell your doctor straight away if you notice any of the following serious side effects -you may need urgent medical treatment:**

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. Hands, feet or genitals may also be affected.
- Liver problems and problems of the pancreas may show as a sudden illness which may happen in the first six months of treatment. This happens in a very small number of people taking Epilim. It includes feeling and being sick many times, being very tired, sleepy and weak, stomach pain including very bad upper stomach pain, jaundice (yellowing of the skin or whites of the eyes), loss of appetite, swelling (especially of the legs and feet but may include other parts of the body), worsening of your fits or a general feeling of being unwell

**Your doctor may tell you to stop taking Epilim immediately if you have these symptoms**

- Severe sometimes life threatening skin reactions (Stevens-Johnson

syndrome, toxic epidermal necrolysis, erythema multiforme).

- There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, or have a history of osteoporosis.
- A decrease in the number of blood platelets (thrombocytopenia); a decrease in the number of red blood cells (anaemia)
- Blood clotting problems (bleeding for longer than normal), bruising or bleeding for no reason
- Changes in mood, loss of memory, confusion, lack of concentration and deep loss of consciousness (coma)
- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism)
- Breathing difficulty and pain due to inflammation of the lungs (pleural effusion)

**Tell your doctor as soon as possible if you have any of the following side effects:**

- Changes in behaviour including being very alert, and sometimes also aggressive, hyper-active and unusual or inappropriate behaviour. This is more likely if other medicines to treat fits such as phenobarbital and topiramate are taken at the same time or if the Epilim starting dose is high or has been suddenly increased
- Changes in the amount of ammonia in the blood. Symptoms of this condition are being sick, problems with balance and co-ordination, feeling lethargic or less alert
- Feeling shaky (tremor), sleepy or unsteady when walking or jerky muscle movements
- Rapid, uncontrollable movement of the eyes
- Feeling sick, stomach ache or diarrhoea, especially when starting treatment. This may be helped by taking Epilim with food or by taking Epilim EC tablets instead
- Extrapyrmidal disorders
- Hearing loss
- Rashes
- Acne
- Hair loss which is usually temporary. When it grows back it may be more curly than before

- Skin rash caused by narrow or blocked blood vessels (vasculitis)
- Changes in women's periods and increased hair growth in women
- Breast enlargement in men
- Swelling of the feet and legs (oedema)
- Weight gain
- Kidney problems, increased need to pass urine
- Headache
- Aggression, agitation, disturbance in attention, abnormal behaviour, restlessness/hyperactivity, and learning disorder
- Tingling or numbness in the hands and feet

Other side effects not listed above may occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

**Storage and Disposal of Epilim**

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 out of the reach and sight of children.
- Do not use Epilim after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Store below 25°C.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

What it looks like

Epilim syrup is a red, cherry flavoured syrup supplied in glass bottles of 300ml.

Ingredients:

Active ingredient:

Each 5ml of the syrup contains 200mg of sodium valproate.

Inactive ingredients: sorbitol (E420), sodium methyl hydroxybenzoate 0.1%, sodium propyl hydroxybenzoate 0.02%, saccharin sodium, sucrose, ponceau 4R (E124, a colourant) and cherry flavour.

MAL Number:

Epilim Syrup 200mg/5ml

**MAL19992701AZ**

**Manufacturer and product registration holder**

Manufacturer

Unither Liquid Manufacturing,  
1-3, allée de la Neste, ZI d'en Sigal  
31770 Colomiers – France.

Product Registration Holder

Sanofi-aventis (Malaysia) Sdn. Bhd.  
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**Date of revision**

This leaflet was prepared on 12 Oct 2015 (based on CCDS V14).

**Serial number**

BPFK(R4/1)061015/00338