

EPILIM CHRONO 500MG/ EPILIM 200 ENTERIC COATED TABLET

Sodium Valproate (500mg/200mg)

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What Epilim is used for

Epilim is used to treat few types of epilepsy (fits) in adults and children. Epilim may also be used to control bipolar disorder, a mental condition with mania symptoms (an elevation of mood).

How Epilim works

- Epilim Chrono (controlled release tablet) is slowly released from the tablets over a period of time.
- Epilim Enteric-coated (EC) have a protective coating that allows it to reach the intestines (gut) without being dissolved in the stomach first. This helps stop it from causing a stomach upset.

Epilim contains a medicine called sodium valproate. This belongs to a group of medicines called anti-convulsants or anti-epileptic agents. It works by helping to calm the brain down.

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.
- You have liver problems or you or your family have a history of liver problems
- You have a rare illness called porphyria (a type 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).

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 have mitochondrial disorders caused by mutations in the nuclear gene encoding mitochondrial enzyme polymerase γ (POLG, e.g. Alpers-Huttenlocher Syndrome) and in children under two years of age who are suspected of having a POLG-related disorder

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
- Do not crush or chew the tablets.
- For Epilim Chrono, take it with or after food. This will help to stop the feelings of sickness that may happen after taking Epilim.
- Epilim EC tablet can be taken twice daily while Epilim Chrono can be taken once or twice daily.

- How much to use

Adults (including the elderly)

- The starting dose is 600mg daily with gradually increment by 200mg every 3 days depending on your condition
- The usual dose is between 1000mg and 2000mg daily. This may be increased to 2500mg.

Children over 20 kilograms

- The starting dose should be 500mg daily. 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

- Epilim EC tablet and Chrono are not recommended in children that weigh under 20kg. Epilim Syrup is recommended instead.

Patients taking other medicines for 'fits' (epilepsy)

- 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.

Patients with mania associated with bipolar disorders

- The starting dose is 1000mg daily. 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 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 women 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 in the first 3 months of the pregnancy using routine antenatal screening blood tests and ultrasound scans.

Pregnant mothers who take Epilim may have babies with:

- Blood clotting problems

- Hypoglycaemia (low blood sugar)
- Hypothyroidism (underactive thyroid gland)

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-feeding 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 other antiepileptic medicines may increase sleepiness.

Side Effect

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

- Rashes, swallowing or breathing problems, swelling of your lips, face, throat or tongue. Hands, feet or genitals may also be affected.
- Liver injury and increased liver enzyme.

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

- Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme.
- Osteopenia and osteoporosis (thinning of the bone) and fractures..
- A decrease in the number of blood platelets and red blood cells.
- Blood clotting problems, 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.
- 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

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Feeling sick, stomach ache or diarrhoea, especially when starting treatment.
- Involuntary muscle movement
- Hearing loss
- Rashes
- Acne
- Hair loss which is usually temporary.
- 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
- Male infertility

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 nppra.moh.gov.my (Public→Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

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 in a dry place below 30°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 Chrono tablets are oval shaped and lilac coloured. The tablets are supplied in blister packs of 30.
- Epilim EC tablets are round and lilac coloured. The tablets are supplied in blister packs of 100.

- Ingredients:

- Each 500mg Chrono tablet contains:
 - Active Ingredient: mixture of 333mg sodium valproate and 145mg valproic acid, equivalent to 500mg of sodium valproate.
 - Inactive ingredient: hypromellose (E464), ethylcellulose, hydrated silica, titanium dioxide (E171), erythrosine BS aluminium lake (E127), indigo carmine aluminium lake FD and C Blue No 2 (E132), iron oxide black (E172), macrogol 400.

- Each 200mg EC tablet contains:
 - Active ingredient:

200mg of sodium valproate.

- Inactive ingredient: povidone (E1201), talc, calcium silicate (E552), magnesium stearate (E572), hypromellose (E464), citric acid monohydrate (E330), macrogol 6000, polyvinyl acetate phthalate, diethyl phthalate, stearic acid (E570), titanium dioxide (E171), Amaranth aluminium lake (E123), indigo carmine lake (E132) and hydroxypropyl cellulose (E463)).

MAL Numbers:

Epilim Chrono 500mg
MAL19910049AZ
Epilim EC tablet 200mg
MAL19860953AZ

Manufacturer

For Epilim Chrono
Sanofi Winthrop Industrie,
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For Epilim EC
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Product Registration Holder

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