EPILIM CHRONO 500MG/ EPILIM 200 ENTERIC COATED TABLET

Sodium Valproate (500mg/200mg)

WARNING

Epilim, Sodium Valproate can seriously harm an unborn child when taken during pregnancy. If you are a female able to have a baby 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.

Schedule an urgent appointment with your doctor if you want to become pregnant or if you think you are pregnant.

You must not stop taking Epilim unless your doctor tells you to as your condition may become worse.

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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*

Bipolar disorder

- For bipolar disorder, you must not use Epilim if you are pregnant.
- For bipolar disorder, if you are a woman able to have a baby, you must not take Epilim, unless you use at least one effective method of birth control (contraception) during your entire treatment with Epilim. You must not stop taking Epilim or interrupt your contraception, until you have discussed this with your doctor. Your doctor will advise you further (see below under "Pregnancy– Important advice for women").

Epilepsy

- For epilepsy, you must not use Epilim if you are pregnant, unless your doctor has determined that no alternative treatment works for you.
- For epilepsy, if you are a woman able to have a baby, you must not take Epilim unless you use at least one effective method of birth control (contraception) during your entire treatment with Epilim. You must not stop taking Epilim or interrupt your contraception, until you have discussed this with your doctor. Your doctor will advise you further (see below under "Pregnancy– Important advice for women").
- If you have a known allergy to sodium valproate (the active ingredient of Epilim) or to any of the other ingredients of Epilim
- If you have an active hepatitis or an active disease of the liver
- If you (or any of your close relatives) have a past history of severe hepatitis, especially when caused by medicines
- If you suffer from hepatic porphyria (a very rare metabolic disease)
- If you have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome)
- If you have a known metabolic disorder, i.e. an "urea cycle disorder"
- If you have an inborn deficiency in carnitine (a very rare metabolic disease) that is untreated.

If you think you may have any of these problems, or if you are in any doubt at all, consult your doctor before taking Epilim.

Before you start to use it

Before taking this medicine, discuss with your doctor:

- If you know or your doctor suspects that there is a genetic problem caused by a mitochondrial disorder in your family, because of a risk of damage to your liver,
- If you are suspected to suffer from any metabolic disorders, particularly hereditary enzyme deficiency disorders such as an "urea cycle disorder" because of a risk of increased ammonia level in the blood,
- If you have a rare disorder named "carnitine palmitoyl transferase type II deficiency", because you are at increased risk of muscle disorders,
- If you have impaired dietary intake in carnitine, found in meat and dairy products, especially in children less than 10 years old,
- If you have an inborn deficiency in carnitine and are taking carnitine,
- If you have systemic lupus erythematosus (a rare disease),
- If you have impaired kidney function. Your doctor may want to monitor valproate level or adapt your dose,
- If you put on weight as your appetite may be increased.

- *Taking other medicines*

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

These medicines and others may be affected by Epilim, or worsen adverse reactions to Epilim, or 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.
Your doctor and pharmacist can give you more information on medicines to be careful with or avoid while taking Epilim.
These include:

- estrogen-containing products (including some birth control pills),
- neuroleptic agents (used to treat psychological disorders),
- medicines used to treat depression,
- benzodiazepines, used as sleeping tablets or to treat anxiety,
- quetiapine, olanzapine (used to treat psychiatric disorders),
- other medicines used to treat epilepsy including phenobarbital, phenytoin, primidone, lamotrigine, carbamazepine, topiramate, felbamate.
- cannabidiol (used to treat epilepsy and other conditions)
- zidovudine (used to treat HIV infections and AIDS),
- mefloquine (used to treat or prevent malaria),
- salicylates (aspirin); see also Child under 3 years of age. "Before you take Epilim",
- anticoagulants (used to prevent clots),
- cimetidine (used to treat stomach ulcers),
- erythromycin, rifampicin,
- carbapenem agents such as imipenem, panipenem and meropenem (antibiotics used to treat bacterial infections). The combination of valproic acid and carbapenems should be avoided because it may decrease the effect of sodium valproate,
- rufinamide,
- acetazolamide,
- protease inhibitors, such as lopinavir, ritonavir (used to treat HIV),
- cholestyramine,
- propofol (used for anaesthesia),
- nimodipine,
- metamizole (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).

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.
- Make sure you keep your regular check-up appointments. They are very important, as your dosage may need to be changed.
- Take this medicine by mouth
- Do not crush or chew the tablets.
- Take Epilim Chrono with or after food. This will help to stop the feelings of sickness that may happen after taking Epilim Chrono.
- 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 or alter your dose without checking with your doctor. If you stop taking the Epilim without your doctor's advice your condition may get worse.

- *If you forget to use it*

Do not take a double dose to make up for forgotten individual doses. Just continue to take your medicine according to your doctor's instructions.
If you have forgotten to take several doses, immediately contact your doctor.

- *If you use too much (overdose)*

An overdose of Epilim may be dangerous. Contact your doctor or the nearest emergency department immediately.

While you are using it

- *Things you must do*

CONTACT A DOCTOR IMMEDIATELY:

- If you or your child develops a sudden illness especially if it is within the first six months of treatment 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, YOU SHOULD CONTACT A DOCTOR IMMEDIATELY. 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

forms of epilepsy,

- Specially if your child is under 3 years of age, Epilim should not be administered together with acetylsalicylic acid (aspirin),
- If you or your child taking Epilim develops problems with balance and co-ordination, feeling lethargic or less alert, vomiting, tell your doctor immediately. This may be due to increased amount of ammonia in the blood.
- As with other antiepileptic drugs, convulsions may become worse or happen more frequently whilst taking this medicine. If this happens contact your doctor immediately.
- A small number of people being treated with anti-epileptics have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- If you or your child develops an allergic reaction, especially with effects on skin and mucosa, and/or fever (see details of symptoms in Side Effects section) contact a doctor immediately.

Children and adolescents
Children and adolescents under 18 years of age:
Sodium valproate should not be used in children and adolescents under 18 years of age for the treatment of mania.

Epilim with food, drink and alcohol
Alcohol intake is not recommended during treatment.

Pregnancy

Important advice for women

You must not stop taking Epilim or interrupt your contraception, until you have discussed this with your doctor. Your doctor will advise you further.

Bipolar disorder

- For bipolar disorder, you must not use Epilim if you are pregnant.
- For bipolar disorder, if you are a woman able to have a baby, you must not take Epilim, unless you use at least one effective method of birth control (contraception) during your entire treatment with Epilim.

Epilepsy

- For epilepsy, you must not use Epilim if you are pregnant, unless your doctor has determined that no alternative treatment works for you.
- For epilepsy, if you are a woman able to have a baby, you must not take Epilim unless you use at least one effective method of birth control (contraception) during your entire treatment with Epilim).

The risks of valproate when taken during pregnancy (irrespective of the disease for which valproate is used)

- Talk to your doctor immediately if you are planning to have a baby or are pregnant.
- Valproate can be harmful to unborn children when taken by a woman during pregnancy.
- The higher the dose, the higher the risks but all doses carry a risk, including when valproate is used in combination with other medicines to treat epilepsy.
- It can cause serious birth defects and can affect the physical and mental development of the child as it grows after 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.
- Hearing problems or deafness have been reported in children exposed to valproate during pregnancy.
- Eye malformations have been reported in children exposed to valproate during pregnancy in association with other congenital malformations. These eye malformations may affect vision.
- If you take valproate during pregnancy you have a higher risk than other women of having a child with birth defects that require medical treatment. Because 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.
- 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.
- Before prescribing this medicine to you, your doctor will have explained what might happen to your baby if you become pregnant whilst taking valproate. If you decide later you want to have a baby you must not stop taking your medicine or interrupt your method of contraception until you have discussed this with your doctor.
- If you are a parent or a caregiver of a female child treated with valproate, you must contact the doctor once your child using valproate experiences her first period.
- Some birth control pills (oestrogen-containing birth control pills) may lower valproate levels in your blood. Make sure you talk to your doctor about the method of contraception (birth control) that is the most appropriate for you.
- Ask your doctor about taking folic acid 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.
- There may also be blood clotting problems, hypoglycaemia and hypothyroidism in the newborn

children of mothers who have taken Epilim during pregnancy.

- There may be a withdrawal syndrome (agitation, irritability, hyperexcitability, jitteriness, hyperkinesia, tonicity disorders, tremor, convulsions and feeding problems), in the new born children of mothers who have taken Epilim during the last trimester of pregnancy.

From the situations described below, please choose those applicable to you and read the corresponding text carefully:

- I am starting treatment with Epilim
- I am taking Epilim and I am not planning to have a baby
- I am taking Epilim and I am planning to have a baby
- I am pregnant and I am taking Epilim

I AM STARTING TREATMENT WITH Epilim

If this is the first time you have been prescribed Epilim your doctor will have explained the risks to an unborn child if you become pregnant. Once you are able to have a baby, you must use at least one effective method of birth control (contraception) without interruption throughout your entire treatment with Epilim. Talk to your doctor or family planning clinic *(to adapt locally)* if you need advice on contraception.

Key messages:

- Pregnancy must be excluded before start of treatment with Epilim through the result of a pregnancy (blood) test, to be confirmed by your doctor.
- You must use at least one effective method of birth control (contraception) during your entire treatment with Epilim.
- You must discuss the appropriate methods of birth control (contraception) with your doctor. Your doctor will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control.
- You must get regular (at least annual) appointments with a specialist experienced in the management of bipolar disorder or epilepsy. During this visit your doctor will make sure you are well aware and have understood all the risk and advice related to the use of valproate during pregnancy.
- Tell your doctor if you want to have a baby.
- Tell your doctor immediately if you are pregnant or think you might be pregnant.

I AM TAKING Epilim AND I AM NOT PLANNING TO HAVE A BABY

If you are continuing treatment with Epilim but you are not planning to have a baby you must use at least one effective method of birth control (contraception) without interruption during your entire treatment with Epilim. Talk to your doctor or family planning clinic *(to adapt locally)* if you need advice on contraception.

Key messages:

- You must use at least one effective method of birth control (contraception) during your entire treatment with Epilim.
- You must discuss the appropriate methods of birth control (contraception) with your doctor. Your doctor will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control.
- You must get regular (at least annual) appointments with a specialist experienced in the management of bipolar disorder or epilepsy. During this visit your doctor will make sure you are well aware and have understood all the risks and advices related to the use of valproate during pregnancy.
- Tell your doctor if you want to have a baby.
- Tell your doctor immediately if you are pregnant or think you might be pregnant.

I AM TAKING Epilim AND I AM PLANNING TO HAVE A BABY

If you are planning to have a baby, first schedule an appointment with your doctor.

You must not stop taking Epilim or interrupt your contraception, until you have discussed this with your doctor. Your doctor will advise you further.

Babies born to mothers who have been on valproate during pregnancy are at serious risk of birth defects and problems with development (behavior and learning disorders) which can be seriously debilitating. Babies are also at risk of lower weight than expected for their age at birth. Your doctor will refer you to a specialist experienced in the management of bipolar disorder or epilepsy, so that alternative treatment options are evaluated early on. Your specialist 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.

Ask your doctor about taking folic acid when planning to have 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.

Key messages:

- You must not stop taking Epilim unless your doctor tells you to.
- You must not interrupt your methods of birth control (contraception) before you have talked to your doctor and worked together on a plan to ensure your condition is controlled and the risks to you and your baby are well understood.
- First schedule an appointment with your doctor. During this visit your doctor will make sure you are well aware and have understood all the risks and advice related to the use of valproate during pregnancy.
- Your doctor might try to switch you to another medicine, or stop treatment with <Invented name several months before you

become pregnant.

- Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant.

I AM PREGNANT AND I AM TAKING Epilim

You must not stop taking Epilim, unless your doctor tells you to as your condition may become worse. Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant. Your doctor will advise you further.

Babies born to mothers who have been on valproate during pregnancy are at serious risk of birth defects and problems with development (behavior and learning disorders) which can be seriously debilitating. Babies are also at risk of lower weight than expected for their age at birth.

You will be referred to a specialist experienced in the management of bipolar disorder or epilepsy, so that alternative treatment options are evaluated.

In the 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.

Ask your doctor about taking folic acid. 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.

Key messages:

- Schedule an urgent appointment with your doctor if you know you are pregnant or think you might be pregnant.
- You must not stop taking Epilim unless your doctor tells you to.
- Make sure you are referred to a specialist experienced in the treatment of epilepsy or bipolar disorder to evaluate the possibility of alternative treatment options.
- You must get thorough counselling on the risks of Epilim during pregnancy, including malformations (birth defects) and physical and mental development disorders in children.
- Make sure you are referred to a specialist for prenatal monitoring in order to examine for potential malformations.

Make sure you read *the patient guide* that you will receive from your doctor. Your doctor will discuss the Annual Risk Acknowledgement Form and will ask you to sign it and keep it. A patient card will also be provided with valproate dispensed at the pharmacy to remind you of the valproate-associated risks when used during pregnancy.

Important advice for male patients able to father a child

Potential risk related to 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 acknowledge the risk and precautions associated with valproate use.

Make sure you read the patient guide that you will receive from your doctor. Your doctor will discuss the Annual Risk Acknowledgement Form and will ask you to sign it and keep it.

Breastfeeding

As only very small amounts of Epilim passes into the breast milk, they do not generally present any risk to the child and weaning is not usually necessary. However, you should discuss with your doctor whether you can breastfeed your baby.

- <u>*Things you must not do*</u>

• 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

Epilim may cause drowsiness or light-headedness in some people, especially at the beginning of treatment or in combination with other antiepileptic drugs or benzodiazepines. Make sure you know how you react to Epilim before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy or light-headed.

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact a doctor immediately if you notice any of the following serious side effects. You may need urgent medical attention:

- Drowsiness, change in consciousness level (including coma), confusion, sluggishness or abnormal behavior and memory loss, associated or not with more frequent or more severe fits, particularly if phenobarbital and topiramate are taken at the same time or if Epilim dose has been suddenly increased.
- Confusion, that could be due to decreased levels of sodium in your blood or to a condition named "SIADH" or Syndrome of Inappropriate Antidiuretic Hormone secretion.
- Problems with balance and co-ordination, feeling lethargic or less alert, associated with vomiting. This may be due to increased amount of ammonia in your blood.
- An increase in the number and severity of convulsions
- Repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness, 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. These may be signs of severe liver or pancreas disorders.
- Allergic reactions which may manifest as:
  - Blisters with skin detachment (blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet) with or without a rash, with sometimes flu-like symptoms such as fever, chills or aching muscle - these may be signs of conditions named 'toxic epidermal necrolysis' or 'Stevens Johnson syndrome')
  - Skin rash or skin lesions with a pink/red ring and a pale center which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These may be signs of a condition named 'erythema multiforme'.
  - An allergy-triggered swelling with painful itchy welts (most often around the eyes, lips, throat and sometimes hands and feet) - these may be signs of "angioedema".
  - Syndrome with skin rash, fever, lymph node enlargement and possible impairment of other organs - these may be signs of a condition named "DRESS" or Drug Rash with Eosinophilia and Systemic Symptoms.
- Spontaneous bruising or bleeding, due to blood clotting problems shown in blood tests
- Severe decrease of white blood cells or bone marrow failure shown in blood tests, sometimes revealed by fever and breathing difficulty
- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism)
- Joint pain, fever, fatigue, rash. These may be signs of systemic lupus erythematosus.
- Shakiness (tremor), uncontrollable muscle contractions, unsteadiness when walking (parkinsonism, extrapyramidal disorder, ataxia)
- Muscle pain and muscle weakness (rhabdomyolysis)
- Breathing difficulty and pain due to inflammation of the envelop of the lungs (pleural effusion)
- Kidney disease (renal failure, tubulointerstitial nephritis) which may manifest as reduced urinary output
- Passing a lot of urine and feeling thirsty (Fanconi syndrome)

Tell your doctor or pharmacist if any of the following side effects get serious or last longer than a few days; you may need medical treatment:

- decreased platelet count or decreased red blood cell count or abnormally increased red blood cell size, or bone marrow disorders (shown in blood tests)
- reduced body levels of vitamin B8 (biotin deficiency)
- headache
- rapid, uncontrollable movements of the eyes
- dizziness
- tingling or numbness of the hands or feet
- double vision
- hearing problems or deafness,
- vomiting, nausea or stomach ache, diarrhoea especially when starting the treatment
- gingival problems (mainly hypertrophia)
- sore mouth, swollen mouth, mouth ulcers and burning feeling of mouth (stomatitis)
- bedwetting or increased need to pass urine, urinary incontinence (unintentional passing of urine)
- skin reactions such as rashes
- transient hair loss, abnormal hair growth, abnormal hair texture, changes in hair color, nail and nail bed disorders, darker areas of skin and mucosae (hyperpigmentation).
- excessive hairiness, particularly in women, virilism, acne (hyperandrogenism)
- irregular or absence of women's period, pain during women's period, cysts in the ovaries (polycystic ovaries)
- male infertility (may be reversible after dose reduction or discontinuation)

- weight gain, obesity
- decrease in carnitine levels (shown in blood or muscular tests)
- inflammation of small blood vessels (vasculitis)
- decrease in body temperature
- swelling of the feet and legs (oedema)
- aggression, agitation, disturbance in attention, abnormal behavior and psychomotor hyperactivity
- learning disorder
- seeing, feeling or hearing things that are not there (hallucinations)
- memory impairment and cognitive disorders

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, have a history of osteoporosis, or take steroids.

Additional side effects in children
Some side effects of valproate occur more frequently in children or are more severe compared to adults. These include liver damage, inflammation of the pancreas (pancreatitis), aggression, agitation, disturbance in attention, abnormal behavior, hyperactivity and learning disorder.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers ➔ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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 oblong, practically white, scored film-coated tablets. The tablets are supplied in tubes 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
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