PACKAGE LEAFLET: INFORMATION FOR THE USER

Epilim® Enteric 200 mg and 500 mg Gastro-resistant Coated Tablets

Sodium valproate

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Is this leaflet hard to see or read? Phone 01 4035600 for help

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 effective method of birth control (contraception) without interruptions during your entire treatment with Epilim. Your doctor will discuss this with you but you must also follow the advice in section 2 of this leaflet.
Schedule an urgent appointment with your doctor if you want to become pregnant or if you think you are pregnant.
Do not stop taking Epilim unless your doctor tells you to as your condition may become worse.

Other sources of information

For the most up to date patient information leaflet and important safety information on this product for girls, women of childbearing potential and male patients, scan the QR code included in this leaflet and on the carton label with a smartphone. The same information is also available on the following URL: qr.epilimandme.ie

Patients should select the electronic patient information leaflet which matches the name of their medicine, the name of this medicine is stated in full at the beginning of this leaflet.

qr.epilimandme.ie

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Epilim EC is and what it is used for
2. What you need to know before you take Epilim EC
3. How to take Epilim EC
4. Possible side effects
5. How to store Epilim EC
6. Contents of the pack and other information

1. What Epilim EC is and what it is used for

What Epilim EC is

The name of your medicine is Epilim Enteric 200 mg and 500 mg Gastro-resistant Coated Tablets (called Epilim EC in this leaflet). ”Enteric coated” means that the tablet has a protective coating that allows it to reach the intestines (gut) without being dissolved in the stomach first. This helps it from causing a stomach upset.

What Epilim EC contains

Epilim EC contains the active substance sodium valproate. It belongs to a group of medicines called anticonvulsants or anti-epileptic agents. It works by helping to calm the brain down.

What Epilim EC is used for

Epilim EC is used to treat epilepsy (fits) in adults and children.

2. What you need to know before you take Epilim EC

Do not take Epilim EC:

Epilepsy

- For epilepsy, you must not use Epilim EC if you are pregnant, unless nothing else works for you.
- For epilepsy, if you are a woman able to have a baby, you must not take Epilim EC unless you use effective method of birth control (contraception) during your entire treatment with Epilim EC. Do not stop taking Epilim EC or your contraception, until you have discussed this with your doctor. Your doctor will advise you further (see below under “Pregnancy, breast-feeding and fertility – Important advice for women”).

- If you are allergic (hypersensitive) to sodium valproate or any of the other ingredients of Epilim EC (listed in Section 6: Further information). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- If you have liver problems or you or your family have a history of liver problems
- If you have a rare illness called porphyria
- If you have a genetic problem causing a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome)
- If you have a known metabolic disorder, i.e. a urea cycle disorder

- If you have a deficiency in carnitine (a very rare metabolic disease) that is untreated

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

Warnings and precautions

Take special care with Epilim EC

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. Epilim can affect the liver and pancreas (see Section 4 below).
- The risk of liver damage is increased if Epilim is taken by children under 3 years of age, in people taking other antiepileptic medicine at the same time or having other neurological or metabolic disease and severe forms of epilepsy.
- 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.
- If your child is under 3 years of age, Epilim should not be administered together with acetylsalicylic acid (aspirin).
- A small number of people being treated with anti-epileptics such as sodium valproate have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- As with other antiepileptic medicines, some patients may experience a worsening of their symptoms (more frequent or more severe convulsions) when taking this medicine. If this happens contact your doctor immediately.
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme and angioedema have been reported in association with valproate treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Check with your doctor or pharmacist before taking your medicine if:

▲ You have diabetes. This medicine may affect the results of urine tests.
▲ You have kidney problems. Your doctor may give you a lower dose.
▲ You have fits (epilepsy), brain disease or a metabolic condition affecting your brain.
▲ You have an illness called ‘systemic lupus erythematosus (SLE)’ - a disease of the immune system which affects skin, bones, joints and internal organs.
▲ You know or your doctor suspects that there is a genetic problem caused by mitochondrial disorder in your family, because of a risk of damage to your liver.

▲ You are suspected to suffer from any metabolic disorders, particularly hereditary enzyme deficiency disorders such as “urea cycle disorder” because of a risk of increased ammonia level in the blood.
▲ You have a rare disorder called “carnitine palmitoyl transferase type II deficiency” because you are at increased risk of muscle disorders.
▲ You have impaired dietary intake in carnitine, found in meat and dairy products, especially in children less than 10 years of age.
▲ You have a deficiency in carnitine and are taking carnitine.
▲ You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking valproate.

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

Children and adolescents

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

Other medicines and Epilim EC

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. Some other medicines may influence the effects of valproate or vice versa. These include:

- Some medicines used for pain and inflammation (salicylates) such as aspirin, see “Take special care with Epilim EC”.
- Some other medicines used to treat fits (epilepsy) – see section 3, “Patients taking other medicines for ‘fits’”. This includes medicines such as phenobarbital, primidone, phenytoin, carbamazepine, topiramate, acetazolamide, lamotrigine, rufinamide and felbamate
- Medicines containing quetiapine, which is used to treat schizophrenia or bipolar disorder
- Clozapine (to treat mental health conditions)
- Medicines used for thinning the blood (such as warfarin)
- Zidovudine - used for HIV infection
- Medicines for depression
- Monoamine oxidase inhibitors (MAOI) such as moclobemide, selegiline, linezolid
- Medicines used to calm emotional and mental conditions such as diazepam and olanzapine
- Propofol, an anaesthetic
- Nimodipine
- Some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine

- Cimetidine - used for stomach ulcers
- Colestyramine used to lower blood fat (cholesterol) levels
- Some medicines used for infections (antibiotics) such as rifampicin and erythromycin
- Lopinavir and ritonavir – used for HIV treatment
- Carbapenem agents (antibiotics used to treat bacterial infections)
- Estrogen-containing products (including some birth control pills)
- Metamizole – used to treat pain and fever
- Cannabidiol (used to treat epilepsy and other conditions)
- Methotrexate (used to treat cancer and inflammatory diseases)
- Some anti-infectives that contain pivalate (e.g. pivampicillin, adefovir dipivoxil)

Epilim EC with alcohol
Alcohol intake is not recommended during treatment.

Weight gain
Taking Epilim EC may make you put on weight. Talk to your doctor about how this will affect you.

Blood tests
Your doctor may wish to do blood tests before you start taking Epilim EC and during your treatment. Blood tests may be required if you are to have surgery, or if you are experiencing unexplained bruising or bleeding.

Pregnancy, breast-feeding and fertility
Important advice for women
You must not stop taking Epilim EC or interrupt your contraception, until you have discussed this with your doctor. Your doctor will advise you further.

Epilepsy
- For epilepsy, you must not use Epilim EC if you are pregnant, unless nothing else works for you.
- For epilepsy, if you are a woman able to have a baby, you must not take Epilim EC unless you use effective method of birth control (contraception) during your entire treatment with Epilim EC. Do not stop taking Epilim EC or your contraception, until you have discussed this with your doctor. Your doctor will advise you further

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 carries a risk if taken 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 tract 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 we know that in women who take valproate around 11 babies in every 100 will have birth defects. This compares to 2-3 babies in ever 100 born to women who don't have epilepsy.
- It is estimated that up to 30-40% of preschool children whose mothers took valproate during pregnancy may have problems with early childhood development. Children affected can be slow to walk and talk , intellectually less able than other children, and have difficulty 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 valporate 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. In women who take valproate, around 11-15 babies in every 100 may have a lower weight than expected for their age at birth. This compares to 5-10 babies in every 100 born to women from the general population.
- 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 child you must not stop taking your medicine or 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 should contact the doctor once your child using valproate experiences menarche.
- 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 be blood clotting problems, such as blood not clotting very well which may appear as bruising or bleeding which takes a long time to stop, hypoglycaemia (low blood sugar), hypothyroidisim (underactive thyroid gland, which can cause tiredness or weight gain) in newborns of mothers who have taken valproate during pregnancy.
- There may be a withdrawal syndrome (including agitation, irritability, hyperexcitability, jitteriness, excessive restlessness and uncontrollable movements (hyperkinesia), muscle problems, tremor, convulsions and feeding problems) in newborns of mothers who have taken valproate during the last trimester of their pregnancy.

Please choose and read the situations which apply to you from the situations described below:

- **I AM STARTING TREATMENT WITH EPILIM EC**
- **I AM TAKING EPILIM EC AND NOT PLANNING TO HAVE A BABY**
- **I AM TAKING EPILIM EC AND PLANNING TO HAVE A BABY**
- **I AM PREGNANT AND I AM TAKING EPILIM EC**

I AM STARTING TREATMENT WITH EPILIM EC

If this is the first time you have been prescribed Epilim EC your doctor will have explained the risks to an unborn child if you become pregnant. Once you are able to have a baby, you will need to make sure you use an effective method of contraception without interruption throughout your treatment with Epilim EC. Talk to your doctor or family planning clinic if you need advice on contraception.

Key messages:

- Pregnancy must be excluded before start of treatment with Epilim EC with the result of a pregnancy test, confirmed by your doctor.
- You must use an effective method of birth control (contraception) during your entire treatment with Epilim EC.
- 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 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 EC AND NOT PLANNING TO HAVE A BABY

If you are continuing treatment with valproate but you are not planning to have a baby make sure you are using an effective method of contraception during your entire treatment with Epilim EC. Talk to your doctor or family planning clinic if you need advice on contraception.

Key messages:

- You must use an effective method of birth control (contraception) during your entire treatment with Epilim EC.
- You must discuss contraception (birth control) 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 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 EC AND PLANNING TO HAVE A BABY

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

Do not stop taking Epilim EC or 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 are at serious risk of birth defects and problems with development which can be seriously debilitating. Your doctor will refer you to a specialist experienced in the management of epilepsy, so that alternative treatment options can be evaluated early on. Your specialist can put several actions in place so that your pregnancy goes as smoothly as possible and any risks to you and your unborn child are reduced as much as possible.

Your specialist may decide to change the dose of Epilim EC or switch you to another medicine or stop treatment with Epilim EC a long time before you become pregnant – this is to make sure your illness is stable.

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 it unlikely that it will reduce the risk of birth defects associated with valproate use.

Key messages:

- Do not stop taking Epilim EC unless your doctor tells you to.

- Do not stop using 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 your baby are reduced.
- 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 advices related to the use of valproate during pregnancy.
- Your doctor will try to switch you to another medicine, or stop treatment with Epilim EC a long time before you become pregnant.
- Schedule an urgent appointment with your doctor if you are or think you might be pregnant.

I AM PREGNANT AND I AM TAKING EPILIM EC

Do not stop taking Epilim EC, 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 are at serious risk of birth defects and problems with development which can be seriously debilitating.

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

In the exceptional circumstances when Epilim EC 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 could 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 are pregnant or think you might be pregnant.
- Do not stop taking Epilim EC unless your doctor tells you to.
- Make sure you are referred to a specialist experienced in the treatment of epilepsy to evaluate the need for alternative treatment options.
- You must get thorough counselling on the risks of Epilim EC during pregnancy, including teratogenicity (birth defects) and physical and mental development disorders in children.
- Make sure you are referred to a specialist for prenatal monitoring in order to detect possible occurrences of 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. You will also receive a Patient Card from your pharmacist to remind you of valproate risks in pregnancy.

Breast-feeding

Very little Epilim EC gets into the breast milk. However, talk to your doctor about whether you should breast-feed your baby. Ask your doctor or pharmacist for advice before taking any medicine.

Important advice for male patients

Potential risks related to taking valproate in the 3 months before conception of a child

A study suggests a possible risk of movement and mental developmental disorders (problems with early childhood development) in children born to fathers treated with valproate in the 3 months before conception. In this study, around 5 children in 100 had such disorders when born to fathers treated with valproate as compared to around 3 children in 100 when born to fathers treated with lamotrigine or levetiracetam (other medicines that can be used to treat your disease).

Other studies did not suggest an increased risk of mental developmental disorders (problems with early childhood development) in children born to fathers treated with valproate in the 3-4 months before conception. In these studies the risk was similar compared to children of fathers treated with lamotrigine or levetiracetam before conception.

Differences in how these studies were designed may explain the different results. Overall, it is not known whether any possible risk of childhood developmental disorders is caused by valproate itself or by other factors, such as the father's underlying medical condition.

As a precautionary measure, your doctor will discuss with you:

- The potential risk in children born to fathers treated with valproate
- The need to consider effective contraception (birth control) for you and your female partner during treatment and for 3 months after stopping treatment
- The need to consult your doctor when you are planning to conceive a child and before stopping contraception (birth control)
- The possibility of other treatments that can be used to treat your disease, depending on your individual situation

Do not donate sperm when taking valproate and for 3 months after stopping valproate.

Talk to your doctor if you are thinking about having a baby.

If your female partner becomes pregnant while you used valproate in the 3 months period before conception and you have questions, contact your doctor. Do not stop your treatment without talking to your doctor. If you stop your treatment, your symptoms may become worse.

You should get regular appointments with your prescriber. During this visit your doctor will discuss with you the precautions associated with valproate use and the possibility of other treatments that can be used to treat your disease, depending on your individual situation.

Make sure you read the patient guide that you will receive from your doctor. You will also receive a Patient Card from your pharmacist to remind you of the potential risks of valproate.

Driving and using machines
You may feel sleepy when taking Epilim EC. If this happens to you, do not drive or use any tools or machines.
Taking other medicines used to treat fits or calm emotional and mental health problems may increase sleepiness.

Epilim EC contains sodium
Epilim EC 200 mg Tablets contains 27.68 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to less than 2% of the recommended maximum daily dietary intake of sodium for an adult.
Epilim EC 500 mg Tablets contains 69.19 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to less than 4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Epilim EC

Female children and women of childbearing potential
Epilim EC treatment must be started and supervised by a doctor specialised in the treatment of epilepsy.

Male patients
It is recommended that Epilim EC is initiated and supervised by a specialist experienced in the management of epilepsy – see section 2 Important advice for male patients.

Always take Epilim EC exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Epilim EC treatment must be started and supervised by a doctor specialised in the treatment of epilepsy.

Taking this medicine
- Your doctor will decide how much Epilim EC to give you or your child depending on your or your child's body weight
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself but ask your doctor

How much to take

Adults (including the elderly)

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

Children over 20 kilograms

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

Children under 20 kilograms

- The usual dose is 20 mg for each kilogram of body weight each day
- Depending on the child's condition your child's doctor may decide to increase this dose

Patients with kidney problems

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

Patients taking other medicines for 'fits' (epilepsy)

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

How to take this medicine

- Take this medicine by mouth
- Take Epilim EC with or after food. This will help to stop the feelings of sickness that may happen after taking Epilim EC
- **Do not** crush or chew the tablets
- The dose is normally split and given half in the morning and half in the evening

If you take more Epilim EC than you should

If you take more Epilim EC than you should, tell a doctor or go to a hospital casualty department straight away.

Take the medicine pack with you. This is so the doctor knows what you have taken.

The following effects may happen: feeling sick or being sick, pupils of the eye become smaller, dizziness, loss of consciousness, weak muscles and poor reflexes, breathing

problems, headaches, fits (seizures), confusion, memory loss, low blood pressure and unusual or inappropriate behaviour.

Taking too much Epilim may result in too much sodium in your blood (hypernatraemia).

If you forget to take Epilim EC

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 stop taking Epilim EC

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

Tests

Make sure you or your child keep your regular appointments for a check up. They are very important as your or your child's dose may need to be changed. Epilim EC can change the levels of liver enzymes shown up in blood tests. This can mean that your or your child's liver is not working properly. If you or your child go into hospital or visit another doctor or a dentist, tell them you are taking Epilim EC.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Epilim EC can cause side effects, although not everybody them.

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

- You have an allergic reaction which may manifest as:
    - Blisters with skin detachment (blistering, peeling or bleeding on any part of your skin (including you 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'. These may happen more often in people also taking lamotrigine.
    - Skin rash or skin lesions with a pink/red ring and a pale centre 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.

- 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.
- Repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness or 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 (see Section 2 above).
- Drowsiness, changes in consciousness level (including coma), confusion, sluggishness or abnormal behaviour 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.
- An increase in the number and severity of convulsions.
- 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, getting more infections than usual.
- 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).
- Difficulty breathing, pain or pressure in the chest (especially when breathing in), shortness of breath and dry cough due to buildup of fluid around the lungs (pleural effusion).
- Kidney disease (renal failure, tubulointerstitial nephritis), which may manifest as reduced urinary output, loss of appetite, feeling and being sick, fits or loss of consciousness.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days; you may need medical treatment, or if you notice any side effects not listed in this leaflet:

Very common (may affect more than 1 in 10 people):

- Nausea

Common (may affect up to 1 in 10 people):

- Decreased platelet count or decreased red blood cell count or abnormally increased red blood cell size, or bone marrow disorders (shown in blood tests)
- Weight gain, obesity

- Seeing, feeling or hearing things that are not there (hallucinations)
- Headache
- Rapid, uncontrollable movement of the eyes
- Hearing problems or deafness
- Vomiting, stomach ache, diarrhoea especially when starting the treatment, see section 2 “How to take this medicine”
- Gingival problems (mainly hypertrophia (overgrowth of gums))
- Sore mouth, swollen mouth, mouth ulcers and burning feeling of mouth (stomatitis)
- Transient hair loss, nail and nail bed disorders
- Urinary incontinence (unintentional passing of urine)
- Pain during women’s period

Uncommon (may affect up to 1 in 100 people):

- Tingling or numbness of the hands or feet
- Inflammation of small blood vessels (vasculitis)
- Skin reactions, such as rashes.
- Abnormal hair growth, abnormal hair texture, changes in hair colour
- Excessive hairiness, particularly in women, male pattern hair growth (virilism), acne (hyperandrogenism)
- Bone 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 any long-term antiepileptic medication, have a history of osteoporosis, or take steroids.
- Irregular or absence of women’s period
- Swelling of the feet and legs (oedema)
- Decrease in body temperature

Rare (may affect up to 1 in 1000 people):

- Aggression, agitation, disturbance in attention, abnormal behaviour and psychomotor hyperactivity
- Learning disorder
- Memory impairment and cognitive disorders
- Double vision
- Bedwetting or increased need to pass urine
- Passing a lot of urine and feeling thirsty (Fanconi syndrome)
- Male infertility is usually reversible after treatment discontinuation and may be reversible after dose reduction. Do not stop your treatment without speaking to your doctor first.
- Cysts in the ovaries (polycystic ovaries)
- Reduced body levels of Vitamin B8 (biotin deficiency), symptoms include a rash occurring around the eyes, nose and mouth, weak brittle nails, hair loss, loss of appetite, nausea, feeling depressed or having hallucinations

Very rare (may affect up to 1 in 10,000 people):

- Breast enlargement in men

Not known (frequency cannot be estimated from the available data):

- Decrease in carnitine levels (shown in blood or muscular tests)
- Darker areas of skin and mucosae (hyperpigmentation)

Blood tests

Epilim EC can change levels of liver enzymes, blood clotting factors, salts or sugars shown up on blood and urine tests.

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 behaviour, hyperactivity and learning disorder.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Epilim EC

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date shown on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not remove the tablets from the foil until just before you take them. Do not cut the blister strips. Store in a dry place. Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other Information

What Epilim EC contains

- Each 200 mg enteric coated tablet contains 200 mg of the active substance, sodium valproate

- Each 500 mg enteric coated tablet contains 500 mg of the active substance, sodium valproate
- The other ingredients are povidone, talc, magnesium stearate, calcium silicate, polyvinyl acetate phthalate, citric acid monohydrate, hypromellose, macrogol 6000, violet lake solids (containing titanium dioxide, amaranth aluminium lake, indigo carmine aluminium lake and hydroxypropyl cellulose), diethyl phthalate and stearic acid

What Epilim EC looks like and contents of the pack
Epilim EC tablets are round and lilac coloured. The tablets are supplied in blister packs of 30, 100 or 112. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
sanofi-aventis Ireland Ltd., T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland
Tel: 00 353 1 4035600
Fax: 00 353 1 4035687
email: IEmedinfo@sanofi.com

Manufacturer
Sanofi-aventis S.A,
Carretera C-35 (La Batlloria-Hostalric), Km 63.09
17404 Riells i Viabrea (Girona)
Spain

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in July 2026.