

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. If you or your child go into hospital or visit another doctor or a dentist, tell them you are taking Epilim.



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

4. Possible side effects

Like all medicines, Epilim can cause side effects, although not everybody gets them. Side effects are more likely to happen at the start of treatment.

Tell your GP, specialist or go to a hospital straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- You have an **allergic reaction** 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 rash), sometimes with flu-like symptoms such as fever, chills, or aching muscles. 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 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'.
 - Allergy-triggered swelling with painful itchy welts (most often around the eyes, lips, throat and sometimes hands and feet) and swallowing or breathing problems. These may be signs of 'angioedema' or an anaphylactic reaction.
 - Syndrome with skin rash, fever, lymph node enlargement and possible impairment of other organs. These may be signs of a condition named 'Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)'.
- 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 sick (nausea) and being sick (vomiting) many times; extreme tiredness, drowsiness and weakness; stomach pain including severe upper stomach pain; yellowing of the skin or whites of the eyes (jaundice); loss of appetite; swelling of the legs and feet (may also 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.
- Blood disorders that can be shown in blood tests. Signs may include:
 - Spontaneous bruising or bleeding due to blood clotting problems or decreased platelet count, or getting more infections than usual (thrombocytopenia)
 - Severe decrease of white blood cells or bone marrow failure, sometimes revealed by fever and breathing difficulty (agranulocytosis)
 - Decreased red blood cell count (anaemia) or abnormally increased red blood cell size (macrocytosis)
 - Bone marrow disorders that affect red blood cells, white blood cells and platelets (pancytopenia)
- Drowsiness, change in consciousness level (including coma), confusion, loss of memory, abnormal behaviour including changes in attention, concentration and mood. This could also be associated with hallucinations or more frequent or severe fits. This is more likely if other medicine 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.
- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism)
- 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)
- An increase in the number and severity of convulsions
- Muscle pain and weakness (rhabdomyolysis)
- Joint pain, fever, fatigue or rash. These may be signs of systemic lupus erythematosus (SLE).
- Problems with balance and co-ordination, feeling lethargic or less alert, associated with being sick (vomiting). This may be due to an increased amount of ammonia in your blood.
- Shakiness (tremor), jerky muscle movements, unsteadiness when walking (parkinsonism, extrapyramidal disorder, ataxia)
- Rapid, uncontrollable movement of the eyes
- Kidney disease or kidney problems (renal failure, tubulointerstitial nephritis and Fanconi syndrome) which may manifest as reduced urinary output or blood in the urine
- Confusion, that could be due to decreased levels of sodium in your blood, identified by a blood test, or to a condition named 'Syndrome of Inappropriate Antidiuretic Hormone (SIADH) secretion'

Tell your GP, specialist or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet:

- Feeling sick (nausea), being sick (vomiting), stomachache or diarrhoea, especially when starting treatment. This may be helped by taking the tablets with food.
- Overgrowth of gums (gingival hypertrophy), swelling of gums or mouth, sore mouth, mouth ulcers and burning feeling of mouth (stomatitis)
- Headache
- Hearing loss, hearing problems or deafness
- Double vision
- Nail and nail bed disorders
- Skin problems such as rashes. These happen rarely, but more often in people also taking lamotrigine.
- Transient hair loss, abnormal hair growth, abnormal hair texture, changes in hair colour
- Darker areas of skin and mucosae (hyperpigmentation)
- Increased levels of some hormones (androgens), which may lead to increased hair growth on the face, breasts or chest (particularly in women), acne or thinning hair

- Skin rash caused by inflammation of small blood vessels (vasculitis)
 - Irregularity or absence of women's period, pain during women's period, cysts in the ovaries (polycystic ovaries)
 - Breast enlargement in men, male infertility (usually reversible after treatment discontinuation and may be reversible after dose reduction. Do not stop your treatment without speaking to your specialist first)
 - Swelling of the feet and legs (oedema)
 - Obesity, weight gain – as your appetite may be increased
 - Bedwetting or increased need to pass urine, urinary incontinence (unintentional passing of urine)
 - Passing a lot of urine and feeling thirsty (Fanconi syndrome)
 - Decrease in carnitine levels (shown in blood or muscular tests)
 - Seeing, feeling or hearing things that are not there (hallucinations)
 - Aggression, agitation, disturbance in attention, abnormal behaviour, restlessness/hyperactivity, memory impairment, or cognitive or learning disorder
 - Tingling or numbness in the hands and feet
 - Lowering of normal body temperature
- There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your GP, specialist or pharmacist if you are on long-term anti-epileptic medication, have a history of osteoporosis, or take steroids.

Tests

Epilim 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), bedwetting (enuresis), renal dysfunction (Fanconi Syndrome), overgrowth of gum tissue, aggression, agitation, disturbance in attention, abnormal behaviour, hyperactivity and learning disorder.

Reporting of side effects

If you get any side effects, talk to your GP, specialist, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Epilim

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 below 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 Gastro-resistant Tablets contain

- Each 200mg gastro-resistant tablet contains 200mg of the active substance, sodium valproate.
- Each 500mg gastro-resistant tablet contains 500mg of the active substance, sodium valproate.
- The other ingredients are 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).

What Epilim Gastro-resistant Tablets look like and contents of the pack

Epilim tablets are round and lilac coloured. The tablets are supplied in blister packs of 30 or 100. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK

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

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Other sources of information

For the most up to date patient information leaflet and important safety information on this product for all patients, scan the QR code included in this leaflet with a smartphone. The same information is also available on the following URL: qr.valproateandme.co.uk

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Epilim® 200mg and 500mg Gastro-resistant Tablets

sodium valproate

sanofi



Is this leaflet hard to see or read?
Phone 0800 035 2525 for help

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.

WARNING

Epilim, sodium valproate, can seriously harm an unborn baby when taken during pregnancy. If you are a female able to have a baby, you must use an effective method of birth control (contraception) at all times during your entire treatment with Epilim. Your specialist will discuss this with you, but you must also follow the advice in section 2 of this leaflet.

Schedule an urgent appointment with your general practitioner (GP) for a referral to a specialist if you want to become pregnant or if you think you are pregnant.

Do not stop taking Epilim unless your specialist tells you to as your condition may become worse.

If you are a parent or caregiver of a female child treated with Epilim, you must also read section 2 of this leaflet carefully and contact your child's GP once they experience their first period, the GP will refer your child to their specialist.

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 GP, specialist or pharmacist.
- This medicine has been prescribed for you. 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 GP, specialist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Epilim is and what it is used for
- What you need to know before you take Epilim
- How to take Epilim
- Possible side effects
- How to store Epilim
- Contents of the pack and other information

1. What Epilim is and what it is used for



What Epilim is

The name of your medicine is Epilim 200mg or 500mg Gastro-resistant Tablets (called Epilim in this leaflet). Epilim 200mg or 500mg Gastro-resistant Tablets are "enteric coated" this means that the tablets have a protective coating that allows them to reach the intestines (gut) without being dissolved in the stomach first. This helps stop them from causing a stomach upset.

What Epilim contains

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

What Epilim is used for

Epilim is used to treat epilepsy (fits) in adults and children. For male patients aged under 55 years not having used valproate before and for female patients aged under 55 years: this medicine is only used when two specialists have agreed that your condition does not respond to other treatments.

2. What you need to know before you take Epilim



Do not take Epilim if:

- You are allergic (hypersensitive) to sodium valproate or any of the other ingredients of Epilim (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have liver problems, or you or your family have a history of liver problems, especially if caused by taking a medicine.
- You have a rare illness called porphyria which affects your metabolism.
- You have a known metabolic disorder, i.e. a urea cycle disorder.
- You have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome).
- You have a deficiency in carnitine (a very rare metabolic disease) that is untreated.
- You are pregnant, unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks (see 'Pregnancy, breast-feeding and fertility – Important advice for women' below).



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- If you are a woman aged under 55 years who is able to have a baby, you must not take Epilim unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks and you use an effective method of birth control (contraception) at all times during your entire treatment with Epilim. Do not stop taking Epilim or your contraception until you have discussed this with your specialist. Your specialist will advise you further (see below under 'Pregnancy, breast-feeding and fertility – Important advice for women').

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



Warnings and precautions

- 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.
- 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 GP or specialist.
- As with other anti-epileptic drugs, convulsions may become worse or happen more frequently whilst taking this medicine. If this happens contact your GP or specialist immediately.
- 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.
- 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.

Talk to your GP, specialist or pharmacist before taking Epilim if:

- You have a brain disease or a metabolic condition affecting your brain.
- You have problems with your pancreas.
- You have diabetes or are being tested for diabetes. This medicine may affect the results of urine tests.
- 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.
- You are suspected to suffer from any metabolic disorders, particularly hereditary enzyme deficiency disorders such as a "urea cycle disorder" because of a risk of increased ammonia level in the blood.
- You have a rare disorder named 'carnitine palmitoyltransferase type II deficiency', because you are at an 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 old.
- You have a deficiency in carnitine and are taking carnitine.
- You have kidney problems. Your specialist may monitor your valproate level or adjust your dose.
- You have an illness called 'systemic lupus erythematosus (SLE)' – a rare disease of the immune system which affects skin, bones, joints and internal organs.
- 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 GP, specialist or pharmacist before taking Epilim.

Weight gain

Taking Epilim may make you put on weight. Talk to your GP, specialist or pharmacist about how this will affect you.

Blood tests

Your GP and/or specialist may request blood tests and liver function tests before and during your treatment with this medicine. Epilim can change the levels of liver enzymes shown in blood tests. This can mean that your or your child's liver is not working properly.

Other medicines and Epilim

Tell your GP, specialist 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. This is because Epilim can affect the way some other medicines work. Also, some medicines can affect the way Epilim works.

In particular, check with your GP, specialist or pharmacist if you are taking any of the following:

- Some medicines used for pain and inflammation (salicylates) such as aspirin.
- 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, rufinamide, topiramate, acetazolamide, lamotrigine and felbamate.
- Cannabidiol (used to treat epilepsy and other conditions).
- Medicines used to calm emotional and mental health disorders (including schizophrenia, bipolar disorder and depression) such as quetiapine, diazepam and olanzapine.
- Monoamine oxidase inhibitors (MAOIs) such as moclobemide (used to treat depression and anxiety), selegiline (used to treat Parkinson's disease), linezolid (used to treat infections).
- Anticoagulants such as warfarin – used to thin the blood and prevent clots. Your doctor may change your dose of the blood thinning medicine and monitor your treatment closely.

