

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking EPILIM.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- EPILIM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

EPILIM® LIQUID SUGAR-FREE (Liquid)

EPILIM® CR 200 (Prolonged release tablets)

EPILIM® CR 300 (Prolonged release tablets)

EPILIM® CR 500 (Prolonged release tablets)

EPILIM® 100 CRUSHABLE (Tablets)

EPILIM® INTRAVENOUS (Freeze-dried powder for intravenous injection)

with **WATER FOR INJECTION – EPILIM®** (Solvent ampoule)

WHAT EPILIM CONTAINS:

EPILIM LIQUID SUGAR-FREE: Contains 200 mg sodium valproate per 5 ml. The liquid also contains sodium methylparabenzoate 0,1 % *m/v* and sodium propylparabenzoate 0,04 % *m/v* as preservatives, as well as hydroxyethylcellulose, sorbitol liquid, saccharin sodium, cherry flavour, Ponceau red colour and citric acid.

EPILIM CR 200: Each tablet contains 133,2 mg sodium valproate and 58,0 mg valproic acid equivalent to 200 mg sodium valproate.

EPILIM CR 300: Each tablet contains 199,8 mg sodium valproate and 87,0 mg valproic acid equivalent to 300 mg sodium valproate.

EPILIM CR 500: Each tablet contains 333,0 mg sodium valproate and 145,0 mg valproic acid equivalent to 500 mg sodium valproate.

Each tablet **EPILIM CR 200, 300** and **500** also contains hypromellose, ethylcellulose, hydrated silica and a violet coat, containing: hypromellose, titanium dioxide, macrogol 400, indigo carmine aluminium lake FD&C blue No.2, erythrosine BS aluminium lake, iron oxide black.

Sugar-free.

EPILIM 100 CRUSHABLE: Each tablet contains 100 mg sodium valproate.

The other ingredients are kaolin light, magnesium stearate, maize starch, silica (colloidal hydrated).

EPILIM INTRAVENOUS: 400 mg freeze-dried sodium valproate per vial,
with **WATER FOR INJECTION - EPILIM:** Each ampoule contains 4 ml sterile water for injection.

WHAT EPILIM IS USED FOR:

The active substance in EPILIM is valproate. EPILIM belongs to a group of medicines used to treat epilepsy (fits) or used to treat and prevent bipolar disorders.

BEFORE TAKING EPILIM:

Do not take EPILIM:

- If you have a known allergy to sodium valproate (the active ingredient of EPILIM) or any of the other ingredients.
- If you are pregnant or breastfeeding your baby.
- If you have an active disease of the liver, including the following:
 - o if you (or any of your close relatives) have a past history of liver dysfunction, especially when caused by medicines.
 - o if you have severe inflammation of the liver (hepatitis).
 - o if you suffer from liver porphyria (a very rare metabolic disease).

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.

Take special care with EPILIM:

- 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, 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 TELL YOUR DOCTOR IMMEDIATELY**. EPILIM can affect the liver (and rarely the pancreas) in a very small number of patients.
- If EPILIM is taken by your child, less than 3 years of age, who is taking anti-epileptic medicine at the same time or has other neurological or metabolic disease and severe forms of epilepsy.
- Especially if your child is under 3 years of age, EPILIM should not be administered together with acetylsalicylic acid (aspirin).
- If you have systemic lupus erythematosus (a rare disease).
- If you 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.

- 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.
- EPILIM may give false-positive readings in the urine-testing of possible diabetics.
- 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.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby while taking EPILIM, please consult your doctor, pharmacist or other healthcare professional for advice.

Usage in pregnancy:

Unplanned pregnancy is not desirable in women receiving EPILIM. You should use an effective method of contraception and **consult your doctor before planning pregnancy.**

EPILIM has no effect on the efficacy of your oral contraceptive pill.

EPILIM may cause an increased risk of birth defect to your developing baby, such as spina bifida (condition where bones of the spine are not properly developed). *In utero* fetal abnormalities, however, can usually be detected in the first part of pregnancy by normal used screening tests.

There may also be blood clotting problems in the new born babies of mothers who have taken EPILIM during pregnancy.

Children born to a mother, who took EPILIM during pregnancy, may have impaired development.

It is therefore essential that you discuss your treatment with your doctor if you are thinking of becoming pregnant or tell your doctor as soon as you know you are pregnant.

Information for women who are planning to get pregnant (see Use in pregnancy):

Consult your doctor **before planning pregnancy.**

Tell your doctor as soon as you know you are pregnant.

Information for women who become pregnant while taking EPILIM (see Use in pregnancy):

If you become pregnant while taking EPILIM, contact your doctor immediately.

Breastfeeding:

EPILIM passes into the breast milk. You should not breastfeed your baby if you are using EPILIM.

Taking other medicines with EPILIM:

Some other medicines may influence the effect of EPILIM or vice versa. These include:

- neuroleptic agents (used to treat psychological disorders)
- medicines used to treat depression
- benzodiazepines, used as sleeping tablets or to treat anxiety
- other medicines used to treat epilepsy including phenobarbital, phenytoin, primidone, lamotrigine, carbamazepine and felbamate
- zidovudine (used to treat HIV infections and AIDS)
- mefloquine (used to treat or prevent malaria)
- salicylates (aspirin), (see also TAKE SPECIAL CARE WITH EPILIM – children under 3 years of age)
- anticoagulants (used to prevent clots)
- cimetidine (used to treat ulcers)
- erythromycin, carbapenem such as imipenem, panipenem and meropenem (antibiotics).

These medicines and others may be affected by EPILIM, or affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of EPILIM with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

HOW TO TAKE EPILIM:

Make sure you keep your regular check-up appointments. They are very important, as your dosage may need to be changed.

Always take EPILIM exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

When treatment is first started you may be prescribed a lower dose. This is because some patients need less EPILIM than others to control their fits. Your doctor will increase the dosage until your condition is controlled. Because of this, it is very important that you follow the instructions your doctor has given you about how much to take. Blood tests may be needed.

EPILIM should preferably be taken with or after food.

The tablets should be swallowed whole, if necessary with a little water (but not with aerated mineral water) and not crushed or chewed.

EPILIM 100 CRUSHABLE tablets may be crushed and mixed with food or drinks.

EPILIM LIQUID SUGAR-FREE should not be diluted.

EPILIM CR is a controlled release formulation of EPILIM and is to be given once or twice daily.

Adults:

The usual dose of EPILIM is between 1 000 mg and 2 000 mg per day but may be increased to 2 500 mg per day. This quantity should be divided and taken in 2 separate doses e.g. half in the morning and half in the evening.

Children over 20 kg:

The usual dose of EPILIM is based on the child's weight as an amount of EPILIM for each kg of body weight. The usual dose is between 20 and 30 mg for each kg of body weight but may be increased to 35 mg for each kg of body weight per day. This quantity should be divided and given in 2 separate doses e.g. half in the morning and half in the evening.

Children under 20 kg:

The usual dose of EPILIM is based on the child's weight as an amount of EPILIM for each kg of body weight. The usual dose is 20 mg for each kg of body weight. This quantity should be divided and given in 2 separate doses e.g. half in the morning and half in the evening.

EPILIM INTRAVENOUS:

The dosage of EPILIM INTRAVENOUS is to be determined and administered by the prescribing doctor.

In the elderly:

Dosage should be determined by seizure control and be recommended by the prescribing doctor.

In people with kidney problems:

The dosage is to be determined by the prescribing doctor as adjustments might be necessary.

Combined therapy:

If you are taking other medicines to control your epilepsy at the same time as EPILIM, your doctor may increase the dose of EPILIM by 5 to 10 mg for each kg of body weight per day.

If you take more EPILIM than you should:

An overdose of EPILIM may be dangerous. **In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.**

If you forget to take EPILIM:

If you miss a dose of EPILIM, take it as soon as you remember. Take any remaining doses for that day at evenly spaced intervals. Do not double the dose.

Effects when treatment with EPILIM is stopped:

Do not stop taking EPILIM or alter your dose without checking with your doctor. If you stop taking the medicine without your doctor's advice, your condition may get worse.

Do not share medicines that are prescribed for you with any other person.

POSSIBLE SIDE EFFECTS

EPILIM may have unwanted side effects. You may need medical treatment if you get some of the side effects:

- nausea and minor gastric irritation, especially when starting the treatment
- shakiness (tremor), drowsiness

- skin reactions such as rashes
- transient hair loss
- changes in women's period
- allergic reactions
- swelling of the feet and legs (oedema)
- weight gain
- kidney problems, bedwetting or increased need to pass urine

Tell your doctor immediately if you notice any of the following serious side effects.

You may need urgent medical attention:

- bizarre behaviour associated or not with more frequent or more severe fits, loss of drive, particularly if phenobarbital is taken at the same time or if EPILIM dose has been suddenly increased
- repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness, loss of appetite, 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
- blood clotting problems
- spontaneous bruising or bleeding
- blisters and skin detachment.

Not all side effects reported for EPILIM are included in this leaflet. Should your general health worsen while taking EPILIM, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of these side effects continue, are severe or bother you, tell your doctor, pharmacist or other healthcare professional.

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or other healthcare professional.

STORAGE AND DISPOSAL INFORMATION:

Do not take this medicine after the expiry date.

EPILIM may spoil if not stored properly. It is very important to keep the tablets in their protective foil until just before you take them.

Store EPILIM at or below 25 °C in a dry place, away from direct sunlight.

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Return unused or expired medicines to your pharmacist for safe disposal.

PRESENTATION:

EPILIM LIQUID SUGAR-FREE is available in amber PET or amber glass bottles of 300 ml.

EPILIM CR 200, EPILIM CR 300, EPILIM CR 500 tablets are available in blister packs, consisting of silver aluminium foil sealed to silver formed aluminium foil (polyamide/aluminium/PVC) and packed in printed cardboard cartons containing 56 or 100 tablets.

EPILIM 100 CRUSHABLE tablets are available in blister packs, consisting of silver aluminium foil sealed to silver formed aluminium foil (polyamide/aluminium/PVC) and packed in printed cardboard cartons containing 100 tablets.

EPILIM INTRAVENOUS: 400 mg of freeze-dried sodium valproate in a clear glass vial supplied with an ampoule of 4 ml of solvent (*WATER FOR INJECTION – EPILIM*).

IDENTIFICATION OF EPILIM:

EPILIM LIQUID SUGAR-FREE:	a red, cherry flavoured liquid.
EPILIM CR 200:	oblong, violet, film-coated tablets.
EPILIM CR 300:	oblong, violet, film-coated tablets.
EPILIM CR 500:	oblong, violet, film-coated tablets.
EPILIM 100 CRUSHABLE:	round, white, scored tablets.

EPILIM INTRAVENOUS: off-white sterile freeze-dried powder in a clear glass vial, and clear, colourless aqueous solvent (*WATER FOR INJECTION – EPILIM*) in a clear glass ampoule.

REGISTRATION NUMBERS:

EPILIM LIQUID SUGAR-FREE:	J/2.5/148
EPILIM CR 200:	27/2.5/0322
EPILIM CR 300:	Y/2.5/286
EPILIM CR 500:	27/2.5/0323
EPILIM 100 CRUSHABLE:	27/2.5/0500
EPILIM INTRAVENOUS:	Y/2.5/43
<i>WATER FOR INJECTION - EPILIM:</i>	Y/34/156

NAME AND ADDRESS OF REGISTRATION HOLDER:

sanofi-aventis south africa (pty) ltd.
2 Bond Street,
Midrand, 1685,
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