





Taking other medicines used to treat fits or calm emotional and mental health problems may increase sleepiness.

3. How to take Epilim Chronosphere

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

Taking this medicine

- Your doctor will decide how much Epilim Chronosphere to give you or your child depending on your or your child’s body weight
- Take this medicine by mouth
- **Do not** crush or chew the granules
- **Do not** store partially used sachets or a mixture of the granules with liquid or food for future use. Always use the full contents of each sachet
- **Do not** sprinkle Epilim Chronosphere on warm or hot foods and drinks, such as soup, coffee, tea, or something similar
- The granules should not be given in babies bottles. This is because they can block the nipple
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself but ask your doctor
- You may see what appears to be complete granules in the patients stools. This is normal as the matrix of the chronosphere granules is not digested by the body. It does not mean that the medicine is not working

How to take this medicine

- This medicine can be taken once or twice daily
- The granules should be sprinkled on a small amount of soft food or drink which should be cold or at room temperature
- This medicine can be taken with soft food or drink such as yoghurt, mousse, jam, ice cream, milk shake and orange juice
- When the granules are put onto food, you must swallow all the food with the granules to make sure you get the correct dose of medicine
- When the granules are swallowed in a drink, the empty glass should be rinsed with a small amount of water. This water should be swallowed because some granules may stick to the glass
- The mixture of granules with food or drink should be swallowed immediately

How much to take

Dosage for Mania:

The daily dosage should be established and controlled individually by your doctor.

**Initial dose:** The recommended initial daily dose is 750mg.

**Mean daily dose:** The recommended daily doses usually range between 1000 mg and 2000 mg.

Dosage for Epilepsy:

- The starting dose for epilepsy is 10-15mg for each kilogram of body weight daily. Your doctor will gradually increase this dose depending on your condition
- For adults the usual dose is generally between 20 and 30mg for each kilogram of body weight daily
- For children the usual dose is generally 30mg for each kilogram of body weight daily

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 Chronosphere. If so, your doctor should gradually initiate treatment depending on you or your child’s condition
- Your doctor may increase the dose of Epilim Chronosphere by 5 to 10mg for each kilogram of body weight each day depending on which other medicines you are taking

If you take more Epilim Chronosphere than you should

If you take more Epilim Chronosphere 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 Chronosphere

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 Chronosphere

Keep taking until your doctor tells you to stop. Do not stop taking Epilim Chronosphere 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 Chronosphere 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 Chronosphere.



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 Chronosphere can cause side effects, although not everybody them.



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

- You have an allergic reaction. The signs may include: a rash, joint pain, fever (systemic lupus erythematosus), swallowing or breathing problems, swelling of your lips, face, throat or tongue. Hands, feet or genitals may also be affected. More severe allergic reactions can lead to lymph node enlargement and possible impairment of other organs.
- 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 Chronosphere. It includes feeling and being sick many times, being very tired, sleepy and weak, stomach pain including very bad upper stomach pain, jaundice (yellowing of the skin or whites of the eyes), loss of appetite, swelling (especially of the legs and feet but may 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 Chronosphere immediately if you have these symptoms
- Kidney problems. Signs may include loss of appetite, feeling and being sick, fits or loss of consciousness
- You have a 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 could be signs of a serious allergy to the medicine called ‘erythema multiforme’
- 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
- Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called ‘Stevens-Johnson syndrome’



- Severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be something called ‘Toxic epidermal necrolysis’
- Bruising more easily and getting more infections than usual. This could be a blood problem called ‘thrombocytopenia’. It can also be due to a fall in the number of white blood cells, bone marrow depression or another condition that affects red blood cells, white blood cells and platelets (pancytopenia) or how the blood clots
- Blood clotting problems (bleeding for longer than normal), bruising or bleeding for no reason
- Changes in mood, loss of memory, confusion, lack of concentration and deep loss of consciousness (coma)
- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism)
- Breathing difficulty and pain due to inflammation of the lungs (pleural effusion)

**Tell your doctor as soon as possible if you have any of the following side effects:**

- Changes in behaviour including being very alert, and sometimes also aggressive, hyper-active and unusual or inappropriate behaviour. 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 Chronosphere starting dose is high or has been suddenly increased
- Changes in the amount of ammonia in the blood. Symptoms of this condition are being sick, problems with balance and co-ordination, feeling lethargic or less alert
- Feeling shaky (tremor), sleepy or unsteady when walking or jerky muscle movements
- Feeling tired or confused with loss of consciousness sometimes accompanied by hallucinations or fits
- Blisters with the skin flaking away
- Rapid, uncontrollable movement of the eyes
- If you feel depressed or have hallucinations, loss of appetite, nausea, have a rash occurring around the eyes, nose, and mouth. These could be signs of biotin deficiency

**Tell your doctor 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, vomiting, red, swollen or bleeding gums, swollen mouth or lips, stomach ache or diarrhoea, especially when starting treatment. Feeling sick may be made better by taking the granules with food
- Fainting
- Nausea
- Sedation
- Extrapyramidal disorders
- Hearing loss
- Skin problems such as rashes. These happen rarely, but more often in people also taking lamotrigine
- Hair loss which is usually temporary. When it grows back it may be more curly than before
- Changes to hair (colour/texture/growth)
- Skin rash caused by narrow or blocked blood vessels (vasculitis)
- Changes in women’s periods and increased hair growth in women, acne or excessively oily skin. Male pattern baldness in women
- Breast enlargement in men
- Male infertility
- Swelling of the feet and legs (oedema)
- Weight gain - as your appetite may be increased
- Kidney problems, bedwetting or increased need to pass urine
- Headache
- Aggression, agitation, disturbance in attention, abnormal behaviour, restlessness, hyperactivity and learning disorder
- Tingling or numbness in the hands and feet.
- Sore muscles and darkened urine (rhabdomyolysis)
- Feeling cold, cold or pale skin, feeling listless and tired (hyperthermia)

Blood tests

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

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Epilim Chronosphere

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 store above 25°C. Store in the original packaging. Do not refrigerate or freeze. Do not use if you notice that any granules have melted or clumped together. 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 Chronosphere contains

- Each sachet of Epilim Chronosphere 100mg Prolonged Release Granules contains 66.66mg sodium valproate and 29.03mg valproic acid. Equivalent to 100mg sodium valproate.
- Each sachet of Epilim Chronosphere 250mg Prolonged Release Granules contains 166.76mg sodium valproate and 72.61mg valproic acid. Equivalent to 250mg sodium valproate.
- Each sachet of Epilim Chronosphere 500mg Prolonged Release Granules contains 333.30mg sodium valproate and 145.14mg valproic acid. Equivalent to 500mg sodium valproate.
- Each sachet of Epilim Chronosphere 750mg Prolonged Release Granules contains 500.06mg sodium valproate and 217.75mg valproic acid. Equivalent to 750mg sodium valproate.
- Each sachet of Epilim Chronosphere 1000mg Prolonged Release Granules contains 666.60mg sodium valproate and 290.27mg valproic acid. Equivalent to 1000mg sodium valproate.
- The other ingredients are hard paraffin, glycerol dibehenate and colloidal hydrated silica.

What Epilim Chronosphere looks like and contents of the pack

- The sachets contain small off -white to slightly yellow, waxy microgranules.
- These modified release granules are supplied in cartons of 30 or 50 sachets. Not all packs/strengths 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: 00353 (0)1 4035600  
Tel: 00353 (0)1 4035687  
email: IEmedinfo@sanofi.com

Manufacturer

Sanofi Winthrop Industrie,  
196, avenue du Maréchal Juin,  
45200 Amilly,  
France

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 January 2015

