

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Epilim® Chronosphere® 100mg Prolonged Release Granules**

**Epilim® Chronosphere® 250mg Prolonged Release Granules**

**Epilim® Chronosphere® 500mg Prolonged Release Granules**

Sodium valproate and Valproic acid

▼ 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 and women of childbearing potential scan the QR code included in this leaflet with a smartphone.

The same information is also available on the following URL:

[qr.epilimandme.ie](http://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](http://qr.epilimandme.ie)

**Read all of this leaflet carefully before you start taking this medicine**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms 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 Chronosphere is and what it is used for
2. What you need to know before you take Epilim Chronosphere
3. How to take Epilim Chronosphere
4. Possible side effects
5. How to store Epilim Chronosphere
6. Contents of the pack and other information

**1. What Epilim Chronosphere is and what it is used for****What Epilim Chronosphere is**

The name of your medicine is Epilim Chronosphere 50, 100, 250 or 500mg Prolonged Release Granules (called Epilim Chronosphere in this leaflet). "Prolonged release" means that the active ingredients (sodium valproate and valproic acid) are slowly released from the granules over a long period of time.

**What Epilim Chronosphere contains**

Epilim Chronosphere contains two medicines called sodium valproate and valproic acid. Both belong to a group of medicines called anticonvulsants or anti-epileptic agents. They work by helping to calm the brain down.

**What Epilim Chronosphere is used for**

Epilim Chronosphere is used to treat epilepsy (fits) in adults and children, and mania.

Epilim Chronosphere is used in the treatment of:

- Epilepsy (fits) in adults and children.
- Mania, where you may feel excited, elated, agitated, enthusiastic or hyperactive. Mania occurs in an illness called "bipolar disorder".

Epilim Chronosphere can be used when lithium can not be used.

**2. What you need to know before you take Epilim Chronosphere****Do not take Epilim Chronosphere:****Bipolar disorder**

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

**Epilepsy**

- For epilepsy, you must not use Epilim Chronosphere 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 Chronosphere unless you use effective method of birth control (contraception) during your entire treatment with Epilim Chronosphere. Do not stop taking Epilim

Chronosphere 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, valproic acid or any of the other ingredients of Epilim Chronosphere (listed in Section 6 below).
- 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

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 Chronosphere.

### **Take special care with Epilim Chronosphere**

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.

### **Children and adolescents**

Children and adolescents under 18 years of age:

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

### **Taking with food and drink**

Alcohol intake is not recommended during treatment.

### **Warnings and precautions**

#### **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 a ‘urea cycle disorder’ where too much ammonia builds up in the body
- You have an illness called ‘systemic lupus erythematosus (SLE)’ - a disease of the immune system which affects skin, bones, joints and internal organs
- You have an underlying condition called "Carnitine palmitoyltransferase type II deficiency" which may increase the risk of muscle damage.
- You know that there is a genetic problem causing a mitochondrial disorder in your family.

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

Some patients who take Epilim Chronosphere experience a worsening of their symptoms (more frequent or more severe convulsions). Contact your doctor immediately.

### **Weight gain**

Taking Epilim Chronosphere 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 Chronosphere and during your treatment.

### **Taking Epilim Chronosphere with other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Epilim Chronosphere can affect the way some other medicines work. Also some medicines can affect the way Epilim Chronosphere works.

### **The following medicines can increase the chance of you getting side effects, when taken with Epilim Chronosphere:**

- 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, topiramate, acetazolamide, lamotrigine, rufinamide and felbamate
- Medicines containing quetiapine, which is used to treat schizophrenia or bipolar disorder

### **Epilim Chronosphere may increase the effect of the following medicines:**

- 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

### **The following medicines can affect the way Epilim Chronosphere works:**

- 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

- Estrogen-containing products (including some birth control pills)
- In particular, tell your doctor or nurse if you are taking any of the following medicines: Carbapenem agents (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.

## **Pregnancy, breast-feeding and fertility**

### **Important advice for women**

#### Bipolar disorder

- For bipolar disorder, you must not use Epilim Chronosphere if you are pregnant.
- For bipolar disorder, if you are a woman able to have a baby, you must not take Epilim Chronosphere, unless you use effective method of birth control (contraception) during your entire treatment with Epilim Chronosphere. Do not stop taking Epilim Chronosphere or your contraception, until you have discussed this with your doctor. Your doctor will advise you further.

#### Epilepsy

- For epilepsy, you must not use Epilim Chronosphere 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 Chronosphere unless you use effective method of birth control (contraception) during your entire treatment with Epilim Chronosphere. Do not stop taking Epilim Chronosphere 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.
- It can cause serious birth defects and can affect the way in which the child develops as it grows. Birth defects which have been reported 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. . Hearing problems or deafness have been reported in children exposed to valproate during pregnancy.
- 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 10 babies in every 100 will have birth defects. This compares to 2-3 babies in every 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 valproate during pregnancy are at increased risk of developing Attention Deficit Hyperactivity Disorder (ADHD).
- 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.

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

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

**I AM STARTING TREATMENT WITH EPILIM CHRONOSPHERE** If this is the first time you have been prescribed Epilim Chronosphere 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 Chronosphere. 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 Chronosphere 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 Chronosphere.
- 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 at immediately if you are pregnant or think you might be pregnant.

**I AM TAKING EPILIM CHRONOSPHERE AND NOT PLANNING TO HAVE A BABY** If you are continuing treatment with Epilim Chronosphere 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 Chronosphere. 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 Chronosphere.
- 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 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 at immediately if you are pregnant or think you might be pregnant.

**I AM TAKING EPILIM CHRONOSPHERE 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 Chronosphere 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 bipolar disorder or 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 Chronosphere or switch you to another medicine or stop treatment with Epilim Chronosphere 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 is unlikely that it will reduce the risk of birth defects associated with valproate use.

**Key messages:**

- Do not stop taking Epilim Chronosphere 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 Chronosphere 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 USING EPILIM CHRONOSPHERE**

Do not stop taking Epilim Chronosphere, 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 bipolar disorder or epilepsy, so that alternative treatment options can be evaluated.

In the exceptional circumstances when Epilim Chronosphere 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 Chronosphere 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 need for alternative treatment options.
- You must get thorough counselling on the risks of Epilim Chronosphere during pregnancy, including teratogenicity and developmental effects 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 Chronosphere 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.

**Driving and using machines**

You may feel sleepy when taking Epilim Chronosphere. 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.

**3. How to take Epilim Chronosphere**

Epilim Chronosphere treatment must be started and supervised by a doctor specialised in the treatment of epilepsy or bipolar disorders.

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 is 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 has 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
- Extrapyrarnidal 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
- Nail and nail bed disorders
- Kidney problems, bedwetting or increased need to pass urine, urinary incontinence (unintentional passing of 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)
- Double vision (rare)

## **Blood tests**

Epilim Chronosphere can change levels of liver enzymes, 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](http://www.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.
- 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

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Tel: 00 353 1 4035687

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#### Manufacturer

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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 2021.**