This medicine is subject to additional monitoring. This will allow quick detection of the occurrence of any unexpected side effects you may get. See the end of section 4 for how to report side effects.

WARNING

Valproate can cause birth defects and problems with early development of the child if taken during pregnancy or if the mother is on this medicine when she becomes pregnant.

Your doctor will discuss this with you but you should also follow the advice in section 2 of this leaflet. Tell your doctor at once if you become pregnant or think you might be pregnant.

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

Key keep this leaflet. You need to read it again if you have any further questions or talk to 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 have any side effects after you have finished taking this medicine, this includes any possible side effects not listed in this leaflet. See section 4.

The name of this medicine is Epilim Chrono 500mg Controlled release tablets. It is to be referred to as Epilim Chrono throughout the remainder of this leaflet. Epilim Chrono is also available in 200mg and 300mg strengths.

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

What is Epilim Chrono and is what it is for used for?

Epilim Chrono is a medicine called 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.

Warning: Epilim Chrono is used for...:

- to treat and control fits (epilepsy), brain disease or a metabolic condition affecting the brain down.
- the active ingredient sodium valproate is slowly released from the tablets over a period of time.

What Epilim Chrono contains

Epilim Chrono 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.

Some of the ingredients in Epilim Chrono are:

- Microcrystalline cellulose (filling material)
- Gelatin (capsules). If you are allergic (hypersensitive) to any of the ingredients listed above, you should not take Epilim Chrono.

What you need to know before you take Epilim Chrono

Do not take Epilim Chrono and tell your doctor if:

- You are allergic (hypersensitive) to sodium valproate or any of the other ingredients of Epilim Chrono (see Section 6: Contents of the pack and other information).
- Signs of an allergic reaction include: a rash, swelling or breathing difficulty, problems swelling of your mouth or tongue.
- You have liver problems or you or your family have a history of liver problem.
- You have a rare illness called porphyria.
- You have a genetic problem caused by a mitochondrial disorder (e.g. Leber-Hand-Schüller-Christian disease).

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 Chrono.

Warnings and precautions

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.

Tell your doctor or pharmacist before taking Epilim Chrono 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 liver (spleen) disease or a metabolic condition affecting your brain.
- You have a ‘use cycle disorder’ where too much ammonia builds up in the body.
- You have an illness called ‘systemic lupus erythematosus (SLE)’ - a disease that affects the immune system which affects skin, joints, brain and internal organs.
- You know that there is a genetic problem caused by a mitochondrial disorder in your family.
- You are pregnant or think you might become pregnant whilst taking Epilim Chrono.

Do not use Epilim Chrono or any of the other medicines you take with Epilim Chrono until your doctor tells you to. Your doctor will need to make sure your epilepsy is controlled and that you are continuing to take the correct combination of Epilim Chrono and carbapenems should be avoided because it may decrease the effect of your medicine. Carbapenems like Cimetidine used for stomach ulcers should not be used with Epilim Chrono.

Taking Epilim Chrono and food and drink

Alcohol intake is not recommended during treatment.

Preconception and breast feeding/fertility

Important advice for women

- If you are of childbearing age, you will need to make sure you can use an effective method of contraception throughout your treatment.
- If you become pregnant whilst taking Epilim Chrono you will need to make sure you and your unborn child are at reduced as much as possible.
- Your doctor will advise you on contraception and what medicine to use.
- You should talk to your doctor before you have a child to ensure your epilepsy is well controlled and that you have an effective method of contraception.
- Tell your doctor at once if you are pregnant or think you might be pregnant.

CONTINUING TREATMENT AND NOT TRYING FOR A BABY

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

Key messages:

- Make sure you are using an effective method of contraception.
- If you have a genetic problem caused by a mitochondrial disorder, you will not be given valproate for your epilepsy.

CONTINUING TREATMENT AND CONSIDERING TRYING FOR A BABY

If you are continuing treatment with valproate and you are now thinking of trying for a baby you must not stop taking valproate yourself whilst taking Epilim Chrono until you have discussed this with your prescriber. Your doctor will tell you what medicine to use during your treatment. Talk to your doctor or family planning clinic if you need advice on contraception.

Key messages:

- Make sure you are using an effective method of contraception.
- Tell your doctor at once if you are pregnant or think you might be pregnant.

UNPLANNED PREGNANCY WHILST CONTINUING TREATMENT

Unplanned pregnancy whilst continuing treatment babies born to mothers who have been on valproate are at serious risk of being born with birth defects. This is because valproate can be very harmful to the unborn child if taken during pregnancy.

Your doctor may decide to change the dose of valproate or switch you to another medicine before you start trying for a baby.

If you develop a mental illness while pregnant you may need to take medicine for your mental health. If you are pregnant whilst taking Epilim Chrono you should talk to your doctor about whether you should breastfeed your baby.

Non-melanoma skin cancers (BCC), squamous cell carcinoma, invasive melanoma, and meningiomas were diagnosed three to four times more often in women who had been taking valproate during the first trimester of pregnancy compared to women who did not take valproate.

It can cause serious effects and can lower the general risk of spina bifida (where the bones of the spine do not fully cover the spinal cord) and other birth defects. This combination of Epilim Chrono and carbapenems should be avoided because it may decrease the effect of your medicine.

Combination of Epilim Chrono and carbapenems should be avoided because it may decrease the effect of your medicine.

[481x945]risk.

If you have any further questions, please ask your doctor or pharmacist.

[528x624]your doctor will advise you what medicine to use during your treatment.

[576x596]else works for you.

[488x449]of your underlying condition and to check how your unborn child is developing.

[533x523]your doctor will discuss this with you.

[566x935]malformations; heart, kidney, liver, brain, internal organs.

[537x954]increases the risk of birth defects associated with valproate use.

[481x907]may develop symptoms of Attention Deficit Hyperactivity Disorder (ADHD).

[537x935]ects and can affect the way in which the child develops as it grows. Birth defects which have been reported include abnormalities of the brain (usually not fully developed); facial and skull malformations; heart, kidney, urinary tract and blood vessels; gastrointestinal malformations; and spina bifida.

[539x870]tory for treating ADHD.

[558x870]years we know that taking valproate around 10 babies in every 150 will have a mental disability and will require extra care. It is estimated that 180-190 boys will be born to women who don't have epilepsy.

[537x907]malformations; heart, kidney, liver, brain, internal organs.

[537x870]t been used for many years we know that in women who take valproate around 10 babies in every 150 will have a mental disability and will require extra care. It is estimated that 180-190 boys will be born to women who don't have epilepsy.

[537x935]ects and can affect the way in which the child develops as it grows. Birth defects which have been reported include abnormalities of the brain (usually not fully developed); facial and skull malformations; heart, kidney, urinary tract and blood vessels; gastrointestinal malformations; and spina bifida.

[537x907]may harm them even if their symptoms are the same as yours.

[537x870]t be born to women of ha...
Driving and using machines:
You may feel sleepy when taking Epilim Chrono. If this happens to you, do not drive or use any tools or machines. Taking other medicines used to treat fits or to calm emotional and mental health problems may increase sleepiness. You may feel sleepy or drowsy when you start taking Epilim Chrono.

3. How to take Epilim Chrono
Always take Epilim Chrono exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Telling your doctor to give you too much medicine could be harmful and even fatal.

Your doctor may tell you to stop taking Epilim Chrono immediately if you have:

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

- Changes in mood, loss of memory, lack of concentration and deep loss of consciousness (coma)
- Underactive thyroid gland, which may cause tiredness or weight gain
- 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:

- Sensitivity of feeling being very alert, and sometimes also aggressive, hyper-active and unusual or inappropriate behaviour. This is more likely to happen in children and young people.
- Changes depending on your age and sex. In particular, thyroid hormones in children and topiramate are taken at the same time if or if the Epilim Chrono starting dose is high or has been suddenly increased.
- Memory loss and unusual or inappropriate behaviour.
- Feeling tired or confused with loss of consciousness sometimes accompanied by hallucinations or fits.
- Blisters with the skin fading away.
- Rapid, unpredictable movement of the eyes

Tell your doctor or pharmacist if any of the following side effects get worse, persist for longer than a few days, or if you notice any side effects not listed in this leaflet:

- Feeling sick, stomach ache or diarrhoea, especially when starting treatment. This may be helped by taking tablets with food or taking the Epilim Gastro-resistant Tablets instead.
- Confusion, fever, headache.
- Skin problems such as rashes. These happen rarely, but more often in people who are also taking lamotrigine.