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

The following medicines can increase the chance of you getting side effects:

• Carbapenem agents (antibiotics used to treat bacterial infections) such as
  • Piperacillin and Tazobactam
  • Meropenem
  • Imipenem and Cilastatin

• Propofol – used for anaesthesia.

In addition, Epilim Chronosphere can interact with certain herbal medicines. If you are unsure about what might happen to your fits, talk to your doctor.

Side effects

Side effects can include:

- Feeling sick, stomach ache, or diarrhea
- Feeling unusually tired
- Feeling generally unwell
- Feeling dizzy or light-headed
- Feeling short of breath
- Feeling cold or hot

If you feel these side effects are getting worse, you should talk to your doctor.

If you are pregnant or think you might be

• I AM PREGNANT AND I AM TAKING EPILIM CHRONOSPHERE
• I AM STARTING TREATMENT WITH EPILIM CHRONOSPHERE
• I AM STOPPING TREATMENT WITH EPILIM CHRONOSPHERE

If you are pregnant or think you might be pregnant:

• You must not use Epilim Chronosphere if you are pregnant or think you might be pregnant. See the end of section 4 for how to report side effects.

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

• Keep this leaflet. You may need to read it again.

• First schedule an appointment with your doctor. During this visit your doctor will make sure you are well aware of and have understood all the risks and advice related to the use of Epilim Chronosphere during pregnancy.

Please check the situations which apply to you and read the information below.

1. TREATING EPILIM CHRONOSPHERE AND TAKING OR NOT TAKING A PILL

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE EPILIM CHRONOSPHERE

3. BEFORE YOU TAKE EPILIM CHRONOSPHERE

4. POSSIBLE SIDE EFFECTS

5. FOR MORE INFORMATION

The following medicines can affect the way Epilim Chronosphere works:

• Some medicines used to treat seizures (such as gabapentin, lamotrigine, levetiracetam, lacosamide, oxcarbazepine, topiramate, and zonisamide)

• Some medicines used to treat infections (such as ciprofloxacin, gentamicin, metronidazole, and telithromycin)

• Some medicines used to treat psychiatric conditions (such as olanzapine, quetiapine, risperidone, and vilazodone)

• Some medicines used to treat depression (such as amitriptyline, mirtazapine, nortriptyline, and venlafaxine)

• Some medicines used to treat pain (such as codeine, tramadol, and ziconotide)

• Some medicines used to treat osteoporosis (such as alendronate, risedronate, and zoledronate)

• Some medicines used to treat heart disease (such as atorvastatin, gemfibrozil, and pravastatin)

• Some medicines used to treat high blood pressure (such as amlodipine, bendroflumethiazide, and metoprolol)

• Some medicines used to treat heart failure (such as angiotensin-converting enzyme inhibitors and angiotensin receptor blockers)

• Some medicines used to treat diabetes (such as metformin, repaglinide, and sulfonylureas)

• Some medicines used to treat asthma (such as beclomethasone, formoterol, and salbutamol)

• Some medicines used to treat high cholesterol (such as ezetimibe, gemfibrozil, and simvastatin)

• Some medicines used to treat liver disease (such as atorvastatin, gemfibrozil, and mevastatin)

• Some medicines used to treat thyroid problems (such as levothyroxine and liothyronine)

• Some medicines used to treat epilepsy (such as carbamazepine, lamotrigine, and oxcarbazepine)

• Some medicines used to treat muscle problems (such as diazepam and olanzapine)

• Some medicines used to treat peptic ulcer disease (such as omeprazole and pantoprazole)

• Some medicines used to treat sleep problems (such as alprazolam, eszopiclone, and zaleplon)

• Some medicines used to treat high blood pressure (such as amlodipine, bendroflumethiazide, and metoprolol)

• Some medicines used to treat heart failure (such as angiotensin-converting enzyme inhibitors and angiotensin receptor blockers)

• Some medicines used to treat diabetes (such as metformin, repaglinide, and sulfonylureas)

• Some medicines used to treat asthma (such as beclomethasone, formoterol, and salbutamol)

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• Some medicines used to treat sleep problems (such as alprazolam, eszopiclone, and zaleplon)
I AM PREGNANT AND I AM USING SPRINTINE CHRONOSPHERE
Do not take SPRINTINE CHRONOSPHERE unless your doctor or pharmacist tells you that it is safe for you to do so. Taking this medicine when you are pregnant can affect your child’s development.

1. Before you start treatment

1.1. Make sure you have read this information leaflet. It contains important information that you should know before you start taking SPRINTINE CHRONOSPHERE.

1.2. If you have any questions about this medicine or any of its possible side effects, please ask your doctor or pharmacist. They may be able to answer any questions you may have.

1.3. This leaflet is intended for use by patients and carers. It does not replace information you have received from your doctor or pharmacist, nor does it take the place of information contained in the Summary of Product Characteristics provided by the manufacturer.

2. Why you are taking SPRINTINE CHRONOSPHERE

SPRINTINE CHRONOSPHERE is used to treat patients who have had seizures in the past and who may take part in the Programme for Epilepsy Surveillance in Pregnancy (PESP). The medicine is used to control and prevent fits and to avoid the need for surgery in some cases. It is used in people who may be having seizures for the first time, and also in people who may be unable to stop having seizures while using other medicines, or who have suffered from seizures due to brain damage or injury.

3. How much to take

3.1. The usual dose is 20mg for each kilogram of body weight.

3.2. This can be increased if needed and should be taken with food at the same time each day until your doctor tells you to stop.

4. How to take this medicine

4.1. The mixture of granules with food or drink should be swallowed.

4.2. The granules should not be given in babies’ bottles.

5. Possible side effects

5.1. Possible side effects of SPRINTINE CHRONOSPHERE may include:

6. Contents of the pack and other information

6.1. Each sachet of 152mg modified release granules contains a mixture of 333.30mg Sodium Valproate and 145.14mg Valproic Acid, equivalent to 500.06mg Sodium Valproate.

7. Export data risks

7.1. If you think you might be pregnant. Your doctor will advise you further.

8. Disposing of any unused medicine

8.1. If you or your child have taken more SPRINTINE CHRONOSPHERE than the recommended dose, tell your doctor immediately.

9. Further information

9.1. Ask your doctor or pharmacist for advice before taking any medicine.

9.2. Please check that you have read and understood this leaflet. It contains important information about your medicine.

10. In case of any additional information

10.1. Your doctor and pharmacist have agreed that this leaflet will be given with each new prescription of SPRINTINE CHRONOSPHERE. This will help you remember to take your medicine and to stop taking it as soon as you are advised.

11. Marketing Authorisation Holder and Manufacturer

11.1. Marketing Authorisation Holder and Manufacturer:

11.2. Marketing Authorisation Holder and Manufacturer and Manufacturer:

11.3. Not all packs/strengths may be marketed

11.4. To view the Product Information and Patient Information for SPRINTINE CHRONOSPHERE, please visit www.mhra.gov.uk/yellowcard