



24 October 2018

Direct Healthcare Professional Communication

Epilim Chronosphere ▼ (sodium valproate) 250mg Modified Release Granules – Temporary shortage in supply until 30 November 2018.

This letter is sent in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA).

Summary

- **Supplies of Epilim 250mg Modified Release Granules are now out of stock. New orders of Epilim Chronosphere 250mg Modified Release Granules will not be fulfilled until 30 November 2018**
- **Supplies of other Epilim formulations, particularly Epilim Liquid and Epilim Syrup, remain available as an alternative, and sodium valproate preparations are also available from other manufacturers**
- **Whenever possible, avoid substitution with 50mg and 100mg Modified Release Granules since this will exhaust the available supply of one or both of these preparations**
- **If an immediate-release formulation (including the liquid or syrup) is substituted, this will need to be given in divided doses, at a minimum twice daily, as opposed to Chronosphere formulations, which may be used once daily**
- **Counsel patients, and parents/caregivers as necessary, so that an unexpected change in preparation does not cause them to stop taking their medication or lead to errors in administration or dosing**

Background

Supplies of Epilim Chronosphere 250mg Modified Release Granules are likely to become exhausted at distribution depots as of the date of this letter. Although individual pharmacies may hold a small supply of this particular preparation, once this has been used new orders will not be fulfilled until distributors have returned to supply, scheduled to be 30 November 2018.

This letter is to alert prescribers and pharmacists to the available alternatives during this out-of-stock period.

Supplies of other Epilim formulations, particularly Epilim Liquid 200mg/5ml and Epilim Syrup 200mg/5ml, remain available as an alternative to Epilim Chronosphere 250mg, and sodium valproate preparations are also available from other manufacturers.

Up until 30 November 2018, Sanofi does not have sufficient stock of lower doses of Epilim Chronosphere Modified Release Granules (50mg and 100mg) to allow substitution of these doses in place of the 250mg preparation. Substitution of these for the 250mg dose will exhaust the available supply of one or both of these preparations in turn, and should therefore be avoided whenever possible.

If prescribers choose to provide an alternative Epilim preparation, they are asked to use Epilim Liquid or Syrup 200mg/5ml whenever possible. These would also be suitable substitutions if Epilim

Chronosphere Modified Release Granules 50mg/100mg become unavailable during the period to 30 November 2018.

Prescribers are reminded that Epilim formulations are interchangeable at the same total daily dose, but that immediate release formulations such as the liquid or syrup need to be given in divided doses, at a minimum twice daily, as opposed to Chronosphere which may be used once daily.

For example, a **once daily** 250mg dose of Epilim Chronosphere Modified Release Granules can be replaced by 125mg Epilim Liquid/Syrup 200mg/5ml **given twice daily**. Alternatively, if the patient takes 250mg of Epilim Chronosphere Modified Release Granules **twice daily**, then this can also be replaced by 250mg Epilim Liquid/Syrup 200mg/5ml given **twice daily**.

Additional advice for the alternative use of Epilim Liquid/Syrup 200mg/5ml: These liquid formulations come with a measuring cup graduated at 5ml, 10ml, 15ml and 20ml. When other doses need to be administered, the pharmacy will supply a syringe (for example a 10ml one with 0.20ml graduation marks). In the case of transforming 250mg of Epilim Chronosphere Modified Release Granules to the liquid/syrup formulation, the patient should receive the closest dose to 6.25ml volume, which will be 6.20ml or 6.40ml, which means the dose will be between 248mg and 256mg, very close to the calculated dose of 250mg.

If using a sodium valproate preparation from an alternative manufacturer, the same level of diligence needs to be taken when determining the dose, and the patient will also need to be counselled so that an unexpected change in preparation does not cause them to stop taking their medication. All patients (and their parent/caregiver as necessary) should be counselled on administration changes to avoid errors in administration and dosing. **Valproate medicines should always be dispensed with a patient information leaflet.**

This shortage has not arisen due to any safety concern. All available preparations of Epilim can continue to be used.

Call for reporting

▼ This medicinal product is subject to additional monitoring. This is intended to facilitate early identification of new safety information. Healthcare professionals are reminded that any suspected adverse events should be reported via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. You can also report suspected adverse events via the Yellow Card app available via the Apple App Store or Google Play Store.

Adverse events arising from the use of medicines manufactured by Sanofi may also be reported to the **Sanofi UK Pharmacovigilance** department at: Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS; Tel: 0800 090 2314; Fax: 01483 554806; Email: uk-drugsafety@sanofi.com.

Company contact point

Should you have any question or require additional information, please contact **Medical Information** at Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK; Tel: 0845 372 7101; Email: uk-medicalinformation@sanofi.com.

Yours faithfully,



Dr Andrew Hockey FFPM

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