NHS Circular: MSAN (2024) 25

Chief Medical Officer Directorate Pharmacy and Medicines Division



17 May 2024

Medicine Supply Alert Notice

Tegretol® (carbamazepine) 100mg/5ml liquid

Priority: Level 2* Valid until: TBC

Issue

- 1. Tegretol® (carbamazepine) 100mg/5ml liquid is out of stock. Resupply date is to be confirmed.
- 2. Generic carbamazepine 100mg/5ml oral suspension sugar free remains available but is unable to support an increase in demand.
- 3. Unlicensed supplies of carbamazepine 100mg/5ml oral suspension can be sourced, lead times vary.

Advice and Actions

- 4. Prescribers should not initiate new patients on Tegretol® (carbamazepine) 100mg/5ml liquid until the shortage has resolved.
- 5. Where patients have insufficient supplies to last until the re-supply date, clinicians and/or pharmacists should:
 - reserve available supplies of generic carbamazepine 100mg/5ml oral suspension for patients who usually receive generic carbamazepine 100mg/5ml oral suspension;
 - consider prescribing and/or supplying unlicensed carbamazepine 100mg/5ml oral suspension, available from Specials manufacturers, ensuring a sugar-free formulation is prescribed for certain patient groups (see Additional information section);
 - consider prescribing and/or supplying unlicensed carbamazepine 100mg/5ml oral suspension from Specialist Importers, which are available in limited quantities, ensuring a sugar-free formulation is prescribed for certain patient groups (see Additional information section);
 - advise patients that this switch is necessary to maintain treatment, and to seek advice if they experience loss of seizure control and/or adverse effects after switching; and
 - if the above options are not considered appropriate, advice should be sought from a specialist clinician on alternative management options.

Additional Information

Clinical Information

^{*}https://www.nss.nhs.scot/media/1842/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.pdf

- 6. Tegretol® (carbamazepine) liquid is licensed for the management of generalised tonic-clonic and partial seizures in epilepsy, the prophylaxis of manic-depressive psychosis in patients unresponsive to lithium therapy, and for trigeminal neuralgia. This formulation is sugar-free.
- 7. Carbamazepine is a <u>category 1 anti-epileptic drug</u> so ideally patients should be maintained on a specific manufacturer's product.

Paediatric patients

- 8. The BNFC recommends the use of sugar-free medicines for long-term treatment in children.
- 9. Children on a ketogenic diet should be on low/no carbohydrate formulations/preparations, where possible. When switching products, the carbohydrate content of the new product should be checked, and dietician consulted on whether the diet needs to be altered to accommodate it.
- 10. Please refer to the links below for further information:
 - SmPC Tegretol[®] 100mg/5ml liquid
 - BNF Carbamazepine
 - BNFC Epilepsy
 - BNF Epilepsy
 - NICE CKS: Epilepsy
 - MHRA anti-epileptic advice on switching products

Guidance on ordering and prescribing unlicensed medicines

- 11. The following Specials manufacturers have confirmed they can manufacture carbamazepine 100mg/5ml oral suspension (please note there may be other companies that can also manufacture supplies):
 - Eaststone (product is sugar-free; carbohydrate content to be confirmed)
 - IPS (product is sugar-free; contains carbohydrates)
 - Nova Laboratories (product contains sugar)
- 12. The following specialist importer has confirmed they can source unlicensed carbamazepine 100mg/5ml oral suspension (please note there may be other companies that can also source supplies):
 - Mawdsleys limited quantities of Timonil[®] (carbamazepine) 20mg/ml liquid sugar free, and Tegretol[®] (carbamazepine) 20mg/ml liquid sugar free have been sourced, lead times vary.
- 13. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Board or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes.
- 14. Please see the links below for further information:
 - The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)
 - <u>Professional Guidance for the Procurement and Supply of Specials</u>, Royal Pharmaceutical Society
 - Prescribing unlicensed medicines, General Medical Council (GMC).

Specialist Pharmacy Service (SPS) website

- 15. The UK Department of Health and Social Care (DHSC) in conjunction with SPS has launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the SPS website. Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
- 16. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

Enquiries

17. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to PharmacyTeam@gov.scot (primary care) or NSS.NHSSMedicineShortages@nhs.scot (secondary care).