Chief Medical Officer Directorate
Pharmacy and Medicines Division



24 July 2024

Medicine Supply Alert Notice

Carbamazepine 100mg/5ml oral suspension sugar free (Accord)

Priority: Level 2*

Valid until: mid-August 2024

Issue

- 1. Carbamazepine 100mg/5ml oral suspension sugar free from Accord is out of stock until mid-August 2024.
- 2. Tegretol[®] (carbamazepine) 100mg/5ml liquid remains available but is unable to support an increase in demand. Please note, Novartis have issued <u>communications</u> regarding the sorbitol content of Tegretol[®] 100mg/5ml liquid and a change to the maximum daily dose.
- 3. Tegretol[®] (carbamazepine) 100mg, 200mg and 400mg immediate release tablets remain available and can support an increase in demand.
- 4. Only carbamazepine 100mg and 200mg immediate release tablets from Medreich remain available and can support an increase in demand.
- 5. Carbamazepine 100mg and 200mg tablets from Crescent are out of stock until mid-August 2024 and therefore cannot support increased demand. See MSAN(2024)16 for further information and refer to the Medicines Supply Tool, on the Specialist Pharmacy Service (SPS) website, for the most up to date information and changes on resupply dates.
- 6. Unlicensed supplies of carbamazepine 100mg/5ml oral suspension can be sourced from Specials manufacturers and specialist importers; lead times vary.

Advice and Actions

- 7. Prescribers should not initiate new patients on carbamazepine 100mg/5ml oral suspension sugar free (Accord) until the shortage has resolved.
- 8. Reserve available supplies of Tegretol® 100mg/5ml liquid for patients who usually receive Tegretol® 100mg/5ml liquid.
- 9. Where patients have insufficient supplies to last until the re-supply date, clinicians should:
 - consider prescribing Tegretol[®] immediate release tablets or generic carbamazepine 100mg and 200mg immediate release tablets (Medreich) in patients able to swallow solid dosage forms;
 - for patients who are unable to swallow solid dosage forms and are on a <u>dose that is</u> <u>equivalent to a whole tablet</u>, consider on a case-by-case basis the off-label crushing and dispersing in water for oral administration of Tegretol[®] immediate release tablets, ensuring this is acceptable to the patient (see Additional information);

- consider unlicensed carbamazepine 100mg/5ml oral suspension (ensuring a sugar-free formulation is prescribed in children):
 - if patients/carers are unable/unwilling to carry out above manipulation (see Additional information)
 - o for those on a non-whole tablet dose
 - o for patients with enteral feeding tubes.

Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see Additional Information section);

- advise and reassure patients that a 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 none of the above options are considered appropriate, advice should be sought from specialists on alternative management options.

Additional Information

10. Carbamazepine 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 treatment of the paroxysmal pain of trigeminal neuralgia. As it is a <u>category 1 anti-epileptic drug</u>, patients with epilepsy should ideally be maintained on a specific manufacturer's product.

Crushing of carbamazepine tablets

- 11. This off-label manipulation should only be considered in patients who require whole tablet doses. Other patient factors to consider when deciding whether to crush tablets include:
 - causing anxiety in some patients stabilised on the liquid or in certain patient groups (e.g. intellectual disabilities) who struggle with changes to routine;
 - some patients may not tolerate the taste of a crushed tablet;
 - some patients/carers may not have sufficient manual dexterity/strength to crush a tablet;
 - risk of tube blockage in tube fed patients
- 12. According to the 'Drug Administration via Enteral Feeding Tubes' resource, "Tegretol tablets (100mg, 200mg, 400mg) disintegrate rapidly when placed in 10mL of water to give a coarse dispersion; this draws up easily into a syringe but the risk of blocking a fine-bore tube is high unless care is taken to keep the granules suspended." No data are available on crushing generic carbamazepine tablets.

Paediatric patients

- 13. The BNFC recommends the use of sugar-free medicines for long-term treatment in children.
- 14. 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.

<u>Links to further information</u>

- SmPC Carbamazepine 100mg/5ml oral suspension
- BNF Carbamazepine
- BNFC Carbamazepine
- Direct Healthcare Professional Communication Tegretol 100mg/5ml liquid
- BNFC Epilepsy
- BNF Epilepsy
- NICE CKS: Epilepsy
- MHRA anti-epileptic advice on switching products

Guidance on ordering and prescribing unlicensed medicines

15. 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; contains carbohydrates)
 IPS (product is sugar-free; contains carbohydrates)

Nova Laboratories (product contains sugar)

• Target Healthcare (product is sugar-free; contains carbohydrates)

- 16. The following specialist importers have confirmed they can source unlicensed Tegretol (carbamazepine) 100mg/5ml oral suspension (please note there may be other companies that can also source supplies). Specialist importers can provide further information as to whether the product contains sugar and carbohydrates:
 - Target Healthcare
 - Mawdsleys
- 17. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and Health 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. Please see the links below for further information:
 - <u>The supply of unlicensed medicinal products</u>, 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

18. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have 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 <u>SPS website</u>. 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.

19. 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

20. 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).