



24 January 2023

Medicine Supply Alert Notice

Vigabatrin (Sabril®) 500mg tablets

Priority: Level 2*

Valid until: w/c 3rd of March 2023

Issue

1. Vigabatrin (Sabril®) 500mg tablets are out of stock until w/c 3rd March 2023.
2. An alternative formulation of the Sabril® brand of vigabatrin is the 500mg granules, which remain available, and will be able to support a full uplift in demand.

Advice and Actions

3. Where patients have insufficient supplies to last until the re-supply date, prescribers should:
 - consider prescribing vigabatrin (Sabril®) 500mg granules in the interim, ensuring that the patient is not intolerant to any of the excipients, is counselled that the dose remains unchanged, and is provided with advice on how to reconstitute the granules (see Additional Information below);
 - advise patients to report any loss in seizure control and side effects after the switch; and
 - if the above options are not considered appropriate, seek advice from specialists on management options.

Additional Information

Clinical Information

4. Vigabatrin (Sabril®) is licensed in combination with other antiepileptic medicines for the treatment of patients with resistant partial epilepsy with or without secondary generalisation, where all other appropriate medicinal product combinations have proved inadequate or have not been tolerated. It is also licensed as monotherapy in the treatment of infantile spasms (West's syndrome).
5. No direct correlation exists between plasma concentration and efficacy; duration of effect is dependent on the rate of GABA transaminase resynthesis rather than the concentration of vigabatrin in the plasma.

6. It is classified by the MHRA as a Category 3 antiepileptic agent, in that essentially, there is complete absorption after oral administration, dose-response curves for efficacy and safety are not steep, and therapeutic index is not narrow.

Administration guidance and advice for vigabatrin granules

- Vigabatrin (Sabril®) tablets and granules have identical licensed indications and dosing.
- The granules are dissolved in half a glass of cold water or soft drink e.g. juice or milk.
- The MHRA guidance on switching antiepileptic drugs notes differences between alternative products (e.g. packaging, appearance, and taste) may be perceived negatively by patients and/or carers, and may lead to dissatisfaction, anxiety, confusion, dosing errors, and reduced adherence. This should be taken into consideration when counselling patients switching to the granules.

Please see the following links for further information

- [BNF vigabatrin](#)
- [SmPC Sabril](#)
- [Antiepileptic drugs: updated MHRA advice on switching between different manufacturers' products](#)

Specialist Pharmacy Service (SPS) website

7. 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.
8. 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 Planning tab and then click on the Medicines Supply option.
9. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool in order to stay up to date concerning medicines supply disruptions.
10. 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

11. 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).