Department of Health & Social Care

NHS England

Medicine Supply Notification

MSN/2023/003

Vigabatrin (Sabril®) 500mg tablets

Tier 2 – medium impact*
Date of issue: 17/01/2023
Link: Medicines Supply Tool

Summary

- Vigabatrin (Sabril®) 500mg tablets are out of stock until w/c 3rd March 2023.
- 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.

Actions Required

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 Supporting 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.

Supporting information

Clinical Information

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).

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.

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.

*Classification of Tiers can be found at the following link:
https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/

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

Enquiries

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk.