



Date: 1st March 2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Sabril 500mg granules for oral solution (vigabatrin): Interim Supply of Italian Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Sanofi is currently experiencing supply disruption with Sabril 500mg granules for oral solution in the UK

To ensure continuity in supply, Sanofi has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply Italian product (BN 2023A - 1800 packs) which is expected to be on the UK market from February 2023 to May 2023.

Please note the following:

- This product is licensed in the UK.
- The product from Italy has the same formulation as the UK product.
- The product from Italy is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the Italian and UK product information, where the carton, leaflet and labelling are presented in Italian language. A comparison between the outer cartons can be found in Annex 1 and Annex 2 of this letter. Please ensure the UK Patient Information Leaflet (PIL) is followed.
- Please discard the Italian leaflet in the pack and refer to the UK approved PIL, which can be found at [Sabril 500 mg granules for oral solution - Patient Information Leaflet \(PIL\) - \(emc\) \(medicines.org.uk\)](#). A copy of the UK approved PIL should be printed and supplied to the patient with their medicine.
- For additional copies of the leaflet, please refer to the link above or contact the company contact point (see next page).
- For Great Britain, the MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Sabril 500mg granules for oral solution that the information must be given in English.
- For Northern Ireland, the exemption is granted under Article 63.3 of Directive 2001/83/EC (as amended).

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

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Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://www.gov.uk/yellowcard>, the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#), and some clinical IT systems (EMIS, SystemOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Suspected adverse reactions should also be reported to Sanofi: Tel: 0800 0902314. Email: UK-drugsafety@sanofi.com.

Company contact point

If you have any questions about this letter or require more information about Sabril 500mg granules for oral solution, please contact Sanofi Medical Information at 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK or telephone 0800 035 2525 or email uk-medicalinformation@sanofi.com

Yours faithfully,

A handwritten signature in black ink, appearing to read "Arunesh Sil".

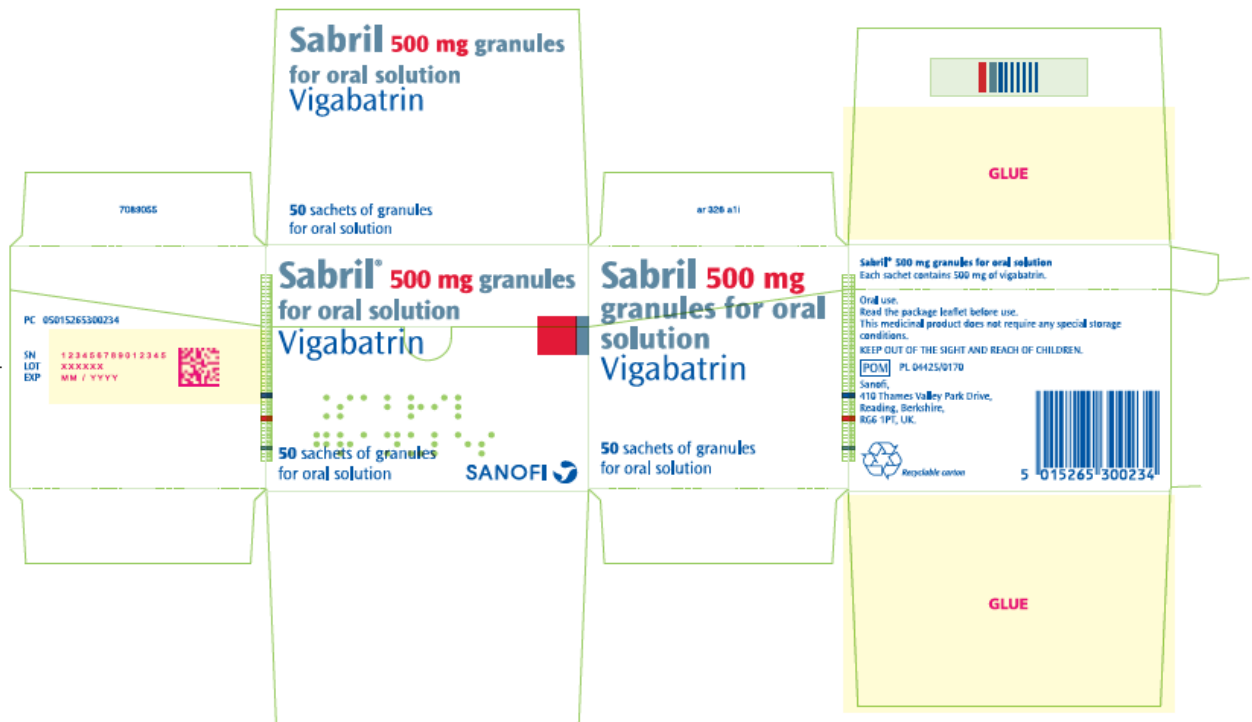
Arunesh Sil
Medical Franchise Lead
General Medicines UKIE

A handwritten signature in black ink, appearing to read "Felicia Pinto".

Felicia Pinto
Head of Regulatory Affairs UKIE

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Annex 1 – Current Approved UK Carton



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Annex 2 – Italian Carton



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