



BATCH RECALL

Product Name	MA No.	Batch No.	Expiry Date
Sabril 500mg Film-Coated Tablets	PA 540/23/1	2006B	11.2025

Wednesday, 12 July 2023

Dear Pharmacist,

We wish to advise you that batch no. 2006B of Sabril 500mg film-coated tablets, PA 540/23/1 is being recalled with immediate effect.

This recall is going to **pharmacy level**.

This action has been agreed with the Health Products Regulatory Authority (HPRA).

The recall has been initiated due to the presence of the impurity tiapride. Although the traces of tiapride detected in the affected batch are below the Permitted Daily Exposure this recall is being undertaken as a precautionary measure to prevent any further exposure.

You are requested to carry out the following actions:

- Immediately identify and quarantine any units from the above batch in your facility. For hospital pharmacies, this includes units at wards, clinics and any other relevant locations within the hospital.
- If you have supplied packs from this batch to any other pharmacy, clinic or other such establishment, please forward a copy of this recall letter to them, and request they quarantine and return any units in their possession to you.
- Return all quarantined and returned units to your wholesaler. Your wholesaler will advise on receiving credit for returned packs by 31 Jul 2023

Unaffected stock of Sabril 500mg Film Coated Tablets is currently available to order.



We apologise for any inconvenience this action may cause. Should you have any queries please contact Sanofi Medical Information at telephone number 01-4035600 or email uk-medicalinformation@sanofi.com

Suspected adverse reactions should be reported to Sanofi Pharmacovigilance at telephone number 01-4035600 or email to IEPharmacovigilance@sanofi.com and to the HPRA using the [online reporting system](#).

Yours faithfully,

A handwritten signature in black ink that reads "R Grundy".

Rod Grundy

Senior Medical Advisor - Foundation Portfolio
General Medicines - UKIE