

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

BATCH RECALL

Wednesday, 12 July 2023

Dear Wholesaler,

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 to **pharmacy level**. A separate recall communication has been sent to pharmacists who have been instructed to return packs to you.

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

The recall has been initiated, as a precaution, due to the presence of trace amounts of the impurity tiapride.

You are requested to carry out the following actions:

1. Immediately identify and quarantine any units of the above product batch, which you have in your possession or are returned to you.
2. Identify whether you have supplied units from this batch to any other wholesaler. If you have done so, please forward a copy of this recall letter to those wholesalers, requesting that they immediately quarantine and return any unsold quantities of this batch to you.
3. Return all quarantined and returned units to Allphar before 31 Jul 2023. Credit will be given for units returned by this date.

Unaffected stock of Sabril 500mg Film Coated Tablets is 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

Yours faithfully,



Rod Grundy

Senior Medical Advisor - Foundation Portfolio
General Medicines - UKIE