



09-Aug-2021

BATCH RECALL

Product Name	MA No.	Batch No.	Expiry Date
Aprovel 150mg Film-coated Tablets	EU/1/97/046/022	0R1VT	Aug-2023
Aprovel 300mg Film-coated Tablets	EU/1/97/046/027	0R1VV	Aug-2023
		0R263	Jan-2023
Co-Aprovel 300mg/12.5mg Film-coated Tablets	EU/1/98/086/017	0R2EL	Aug-2023

Dear Wholesaler,

Sanofi-Aventis Ireland Ltd wish to inform you that the above 3 batches of Aprovel Film-coated Tablets and 1 batch of CoAprovel Film-coated Tablets are 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 is as a precautionary measure, due to the presence of an azide impurity above the acceptable regulatory limit.

This recall communication has also been sent to pharmacists who have been instructed to return packs to their wholesaler by 24-Aug-21 to be eligible for credit.

You are requested to:

1. Immediately identify and quarantine any units of the above batches, which you have in your possession or are returned to you.
2. Identify whether you have supplied units from these batches 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 these batches to you.
3. Return all quarantined and returned packs to Allphar before 07-Sep-21. Credit will be given for packs returned by this date



Unaffected stock of Aprovel 75mg Film-coated Tablets, Aprovel 300mg Film-coated Tablets and CoAprovel 300mg/25mg Film-coated Tablets is available to order. Please consult the Shortages section of the HPRA website for up to date information on when supply of other Aprovel and CoAprovel products will be available.

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 sincerely,

A handwritten signature in black ink that reads "Linda Cleary".

*Electronically signed
By: Linda Cleary
Reason: Approved
Date: Aug 5, 2021
17:08 GMT+1*

Linda Cleary PhD
Country Quality Head