



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
CoAprovel 300mg/12.5mg Film-coated Tablets	EU/1/98/086/017	0R2EL	Aug-2023

Dear Pharmacist,

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**. Please note there is **no** requirement to contact patients, as this is a pharmacy level recall only.

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.

The impurity has been recently confirmed as mutagenic. A mutagenic impurity may have the potential to be carcinogenic; however, no link has been established at present, and there is no evidence that this impurity has caused any harm to patients. This recall is being undertaken as a **precautionary measure** to prevent any further exposure to the impurity, above regulatory acceptable levels, whilst the investigation is ongoing.

#### You are requested to:

1. Immediately quarantine any units from the batches / products listed in the letter. For hospital pharmacies, this will include units at wards, clinics and any other relevant locations within the hospital.
2. If you have supplied packs from these batches 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.
3. Return the quarantined and returned units to your wholesaler. The wholesaler will be in a position to advise on receiving credit for returned packs by 24-Aug-21.

Similar recalls are happening across Europe at this time, and patients may contact you with questions about the issue. Patients can be advised that this is a precautionary recall and that there is no immediate risk presented by the impurity.

**Patients should be advised that they should not abruptly stop taking their medicine.**

Unaffected stock of Aprovel 75mg Film-coated Tablets, Aprovel 300mg Film-coated Tablets and CoAprovel 300mg/25mg Film-coated Tablets is available to order from your wholesaler. 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](mailto:uk-medicalinformation@sanofi.com)

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

Yours sincerely,



Electronically signed  
by: Linda Cleary  
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17:06 GMT+1

Linda Cleary PhD  
**Country Quality Head**