PHARMACEUTICAL
COSMETICS AND
OVER THE COUNTER PRODUCTS

Unit 10 Ashbourne Business Park, Rath, Ashbourne, Co. Meath
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BATCH RECALL

CoAprovel 300 mg/12.5 mg film-coated tablets, EU/1/98/086/017

Batch No.	Expiry Date
FT013::RN248	02/2023

Parallel distributed by PCO Manufacturing Ltd

August 05th 2021

Dear Pharmacist,

We wish to advise you that the above listed batch of CoAprovel 300 mg/12.5 mg film-coated tablets is 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.

We kindly request that the following actions are carried out:

1. Immediately identify and quarantine any units from the above-listed batch within your pharmacy. For hospital pharmacies, this includes units at wards, clinics and any other relevant locations within the hospital.

2. 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 unused units to you.

3. Please contact PCO's Customer Service Department on 01-8356700 to arrange uplift of quarantined units within 14 days. Credit will be issued for packs returned by August 20th 2021.

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.**

Suspected adverse reactions should be reported to PCO by email (nclarke@pco.ie) and to the HPRA by email *(medsafety@hpra.ie)* or using the HPRA online ADR report form.

If you have any further questions regarding the contents of this letter, please contact Niamh Clarke at 01-8356700.

We apologise for any inconvenience that this situation may have caused.

Yours sincerely,

Niamh Clarke, MPSI, QP, RP
Head of Quality & Regulatory Affairs
Email: nclarke@pco.ie