

Batch Recall**Ketofall 0.25 mg/ml eye drops, solution in single-dose container, PA1815/002/001**

Batch Numbers	Expiry Dates
21M066	30.11.2023
22C035	29.02.2024
23A028	31-01-2025

07/09/2023

Dear Pharmacist

We wish to advise you that the above batches of Ketofall 0.25 mg/ml eye drops, solution in single-dose container, PA1815/002/001 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 reason for the recall is due to a deviation in the manufacturing process where filters were reused in the manufacturing of the above product.


We request that the following actions are carried out:

1. Please check your current inventory and immediately quarantine any units of the above batches within your pharmacy. For hospital pharmacies, this includes units at wards, clinics and any other relevant locations in the hospital.
2. If you have supplied units from the batches above to any other pharmacy, clinic or other such establishments, please forward a copy of this recall letter to them and request they quarantine and return any unused units to you.
3. Please contact your wholesaler to request an uplift of the affected stock. Full credit or replacement stock will be provided for stock that has been arranged for uplift prior to the 21st Sept 2023.

Unaffected stock of this product is available to order through your wholesaler.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Helena Kennedy Quality Manager Scope Eyecare at telephone number +353 1 525 3683.

Yours sincerely,



Dr. Karl Luschmann
Qualified Person

Pharma Stulln GmbH

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