pharma **STULLN**

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 Wholesaler,

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.

You are requested to please carry out the following actions:

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(s). 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 the batches to you.
3. Return all quarantined and returned units to United Drug before 5th Oct 2023. Credit or replacement stock will be provided for units returned by this date.

Unaffected stock of this product is available to order.

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

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Geschäftsführer:
Dr. Karl Luschmann
Sitz des Unternehmens: Stulln
Registergericht: Amberg HRB 778
Erfüllungsort und Gerichtsstand: Schwandorf
Ust-Id-Nr.: DE 811 541 951, **St.-Nr.** 211/135/10207

Bankverbindung:
UniCredit Bank AG (HypoVereinsbank) Amberg
Konto: 1 364 430
BLZ: 752 200 70
IBAN: DE 92 7522 0070 0001 3644 30
S.W.I.F.T. (BIC): HYVEDEMM405

Sparkasse im Landkreis Schwandorf
Konto: 570 101 311
BLZ: 750 510 40
IBAN: DE 73 7505 1040 0570 1013 11
S.W.I.F.T. (BIC): BYLADEM1SAD