

Théa Pharma Ltd.

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Batch Recall

Zaditen 0.25 mg/ml, eye drops, solution, PA1107/010/001 Batch Number 4V64; Expiry Date 09 2026

11th July 2025

Dear Pharmacist,

We wish to advise you that batch no. 4V64 of Zaditen 0.25 mg/ml, eye drops, solution is being recalled as a precautionary measure with immediate effect.

This recall is going to **pharmacy level** and the action has been agreed with the Health Products Regulatory Authority (HPRA).

The reason for the precautionary recall is a potential lack of assurance regarding the sterility of units from the above referenced batch, following the occurrence of an environmental microbial contamination incident at the manufacturing site.

Please perform the following actions:

- 1. Immediately quarantine any units from batch no. 4V64 which you have in your pharmacy. For hospital pharmacies, this includes stock on wards, in clinics and at any other relevant locations within your hospital.
- 2. If you have supplied units from the batch to any other pharmacy, clinic or other such healthcare establishment, forward a copy of this recall letter to them, requesting that they immediately quarantine and return any unused units to you.
- 3. Contact your supplier to arrange the return of quarantined stock. Full credit will be issued for stock returned by 25th July 2025.

Alternative replacement stock is currently not available to order. We anticipate our next delivery of this product will take place in early 2026.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Theapharma Limited by email at <u>info@theapharma.ie</u> or by telephone at 094 925 0290.

Yours sincerely,

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Diarmuid Gavin Country Manager