



MEDICINES RECALL

CLASS 2 MEDICINES RECALL, EL(25)A/34

Action within 48 hours

Issued 07 July 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Laboratoires Théa

MEDICINE DETAILS

Zaditen 0.25 mg/ml, eye drops, solution

PL: 20162/0019

Active Ingredient: ketotifen fumarate

SNOMED code: 388511000001106

GTIN: 3662042000874

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
4V64	30/09/2026	5ML	27/01/2025

Background

Laboratoires Théa trading as Thea Pharmaceuticals Limited have notified the MHRA of an out of specification event related to environmental monitoring during manufacturing, which may increase the risk of microbial contamination of the medicinal product. As a precautionary measure the specific batch mentioned in this notification is being recalled. To date, Thea Pharmaceuticals Limited have not received any reports of adverse incidents or product quality complaints related to this potential defect.

Advice for Healthcare Professionals:

Stop supplying the above batch immediately. Quarantine all stock and return it to your supplier using your supplier's approved process.

Thea Pharmaceuticals can confirm 11,360 packs of this batch were released and distributed, no reported adverse events or product quality complaints received to date.

Advice for Patients:

No further action is required by patients as this is a Pharmacy and Wholesaler level recall related to a specific batch of Zaditen 0.25 mg/ml, eye drops, solution.

Whilst the recall is precautionary and no adverse events have been reported by Thea Pharmaceuticals Limited, if any side effects were to be observed, these would be related to ocular infection and may include conjunctivitis, keratitis, and/or blepharitis, or, for susceptible patients, could be a more severe infection. Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Additional information:

For stock control enquiries please contact:

- For pharmacies supplied by a wholesaler, returns should be made via the wholesaler.
- For wholesalers, please contact Mawdsleys PreWholesaler (MPW) customer services using e-mail address customer.services@mpwpharma.co.uk.
- For healthcare establishments: please arrange local destruction and make a claim through Mawdsleys PreWholesaler customer.services@mpwpharma.co.uk.

For more information or medical information please call 0345 521 1290 (and select option 3) or e-mail thea-pharma@medinformation.co.uk

For stock control enquiries please email customer.services@mpwpharma.co.uk.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

**Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU**

Telephone +44 (0)20 3080 6574

DMRC@mhra.gov.uk