



MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 Days
Pharmacy/Wholesaler Level Recall

Date: 15 March 2021

EL (21)A/08

Our Ref: MDR 219-02/21

Dear Healthcare Professional,

Thame Laboratories

Itraconazole 10mg/ml Oral Solution

PL 39307/0069

Batch Number	Expiry Date	Pack Size	First Distributed
L465	03/2022	150 ml	25 Jan 2021
L475	03/2022	150 ml	25 Jan 2021

Active Pharmaceutical Ingredients: Itraconazole

Brief description of the problem

Thame Laboratories are recalling the above batches due to an issue with the container closure (child-resistant cap). The Marketing Authorisation Holder has received a number of complaints regarding the child-resistant caps which were difficult to open, and their investigation has identified an issue with the bottle capping process during the manufacture of the product.

Advice for healthcare professionals

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

Further Information

For more information or medical information queries, please contact customer.services@syrimed.co.uk

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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