



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 hours
Pharmacy/Wholesaler Level Recall

Date: 04 July 2024

EL (24)A/26

Our Ref: MDR 098-04/24

Dear Healthcare Professional,

Kent Pharma UK

Itraconazole 10mg/ml Oral Solution

PL 51463/0099

SNOMED Code 26421511000001104

Batch No	Expiry Date	Pack Size	First Distributed
231069	Dec/2024	150ml	Oct/2023
231071	Dec/2024	150ml	Oct/2023

Active Pharmaceutical Ingredient: Itraconazole

Brief description of the problem

Kent Pharma UK is recalling the above batches of Itraconazole 10mg/ml Oral Solution as a precautionary measure due to out of specification in the appearance of the solution, particularly the presence of suspended particles or clusters of crystals. Initial investigations indicate that this is a solubilisation issue of the active ingredient for the above batches. This means that there is the potential for some doses to have lower active ingredient (itraconazole) in solution. The root cause of this issue is under investigation, but based on the potential for underdosage, the impacted batches are being recalled as a precautionary measure.

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.

Advice for patients

No further action is required by patients as this is a Pharmacy/Wholesaler level recall. The impacted batches may exhibit suspended particles or clusters of crystals, which present no direct harm, however it may mean that some doses have lower active ingredient (itraconazole) in solution. This is unlikely to impact the effectiveness of your treatment and the recall is a precautionary measure. If you have any concerns, please speak to a healthcare professional.

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](#).



Medicines & Healthcare products Regulatory Agency

Further Information

For medical information enquiries please contact medical@kent-athlone.com

For stock control enquiries please contact customer.services@kent-athlone.com

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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