Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL, EL(25)A/23

Action within 48 hours

Issued 22 May 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Aspen Pharma Trading Limited

MEDICINE DETAILS

Mercaptopurine 50mg tablets

PL: 39699/0047 Active Ingredient: mercaptopurine SNOMED code: 22519811000001102 GTIN: 05060598250817

AFFECTED LOT BATCH NUMBERS			
Batch No.	Expiry Date	Pack Size	First Distributed
P0010384	31/12/2028	25	08/01/2025

Background

Aspen Pharma Trading Limited is recalling a specific batch of Mercaptopurine 50mg tablets as a precautionary measure due to microbial contamination following a small number of complaints of discoloured tablets within the packs, identified when the packs have been opened by healthcare professionals. The contamination has been identified as Penicillium Kongii.

Advice for Healthcare Professionals:

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

Advice for Patients:

Patients or carers should check to see if they have received tablets from the listed batch of Mercaptopurine 50 mg tablets (Batch P0010384). The batch number can be found on the label of the medicine bottle.

The tablets should be a 'pale yellow colour and are marked with 'PT / 50', as per the Patient Information Leaflet (PIL). If you have tablets that are discoloured in any way, from the affected batch please contact your relevant healthcare professional responsible for your treatment, e.g. specialist or prescriber.

Patients should not stop taking their medication without discussing this with their specialist or prescriber as there may be a need for additional monitoring.

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 <u>MHRA Yellow Card scheme</u>.

Additional information:

For all medical information enquiries and information on this product, please email <u>Aspenmedinfo@professionalinformation.co.uk</u> or telephone 01748 828391. For stock control enquiries please email <u>uk.stockenquiries@aspenpharma.eu</u>

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

Defective Medicines Report Centre 10 South Colonnade Canary Wharf London E14 4PU Telephone +44 (0)20 3080 6574 / <u>DMRC@mhra.gov.uk</u>