National Patient Safety Alert

Medicines & Healthcare products Regulatory Agency

Recall of Quetiapine Oral Suspension (unlicensed medicine), manufactured by Eaststone Limited due to a potential for overdosing

Date of Issue:	29-Jan-26	Reference No:	NatPSA/2026/002/MHRA

This alert is for action by: primary and secondary care, specifically those involved in pharmacy services, including dispensing general practices and those involved in the prescribing for mental health conditions.

Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards) supported by Chief Pharmacists, as well as leaders in general practice and community pharmacy.

Explanation of identified safety issue:

Eaststone Limited have informed MHRA that the formula they have used to manufacture all batches of quetiapine oral suspension products is incorrect. The active content is twice the amount that it should be which could lead to overdosing.

Eaststone Limited have clarified that a total of 166 units/bottles were manufactured between 26 October 2025 and 26 January 2026 and distributed to healthcare customers. The remainder of bottles have been quarantined and will not be supplied. This notification includes batches that have expired. Eaststone Limited have confirmed that they can trace supply to all healthcare customers who have been supplied with the impacted products.

Any patients who have taken batches, including both expired and non-expired should be reviewed.

Patients should be advised not to stop any treatments without consulting their relevant healthcare professional and a treatment review should be initiated as soon as possible.

Withdrawal of antipsychotic drugs after long-term therapy should always be gradual and closely monitored to avoid the risk of acute withdrawal syndromes or rapid relapse. Patients should be monitored for 2 years after withdrawal of antipsychotic medication for signs and symptoms of relapse.

Healthcare professionals should be aware of and discuss the risk of overdose which can present as severe central nervous system depression (sedation, coma, respiratory depression), confusion and agitation, seizures tachycardia, and hypotension with patients and advise them to contact the healthcare professional responsible for their care, or their community psychiatric nurse, or carer to seek medical attention if these symptoms develop.

Actions required

Actions to complete by 05-Feb-2026

The action to recall should be coordinated by the Chief Pharmacist/Superintendent Pharmacist or Responsible Pharmacist and Dispensing GPs in the first instance, with support from other HCPs.

1. Stop supplying the Eaststone Limited product immediately. Quarantine all remaining stock and return it to your supplier using your approved process.

2. Eaststone Limited have full traceability of healthcare customers they have supplied directly and have already initiated communication and recall action, therefore most healthcare professionals will be made directly aware via the company.

3. Pharmacy professionals and other healthcare professionals involved in dispensing medicinal products should identify and immediately contact all patients who have been dispensed the impacted products and ask them to confirm if they have remaining stock within their possession. If batch/product traceability information is not available, all patients dispensed this product since 26 October 2025 to 26 January 2026 should be contacted.

4. If any patients are identified with this product, pharmacy professionals and other healthcare professionals involved in dispensing should also contact the patients GP, or healthcare professional responsible for the care of the patient if this information is available (e.g. specialist prescriber or nurse) and advise that the patient may have taken twice the intended dose due to a manufacturing error. Therefore, immediate ongoing treatment of the patient needs to be reviewed. As this is a specialist use product, patients may require plasma level monitoring and ECG and other clinicians and healthcare professionals may need to be involved in the patients review and to consider alternative treatment options, where appropriate.

For further detail, resources and supporting materials see: alert on MHRA website

For any enquiries about this alert contact: info@mhra.gov.uk

Additional information:

LICENCE HOLDER	MEDICINE DETAILS	AFFECTED LOT/BATCH NUMBERS
Eaststone Limited (unlicensed manufacturer), MS 32967	Quetiapine 12.5 mg/5 ml Oral Suspension	Annex 1 in recall document
	Quetiapine 25 mg/5 ml Oral Suspension	Annex 2 in recall document
	Quetiapine 50 mg/5 ml Oral Suspension	Annex 3 in recall document
	Quetiapine 100 mg/5 ml Oral Suspension	Annex 4 in recall document
	Quetiapine 200 mg/5 ml Oral Suspension	Annex 5 in recall document

Defective Medicines Report Centre Reference: 38317654

Distribute to Patient, Pharmacy and Wholesaler Level

Advice for Healthcare Professionals to Provide to Patients:

A manufacturing error has been identified for all batches of quetiapine oral suspension made by Eaststone Limited which means the product contains twice as much quetiapine compared to the amount that was prescribed.

Your pharmacist or other healthcare professionals should contact you if you have been dispensed the impacted products and ask you to confirm if you still have some medicine within your possession.

However, it is important that if you are taking quetiapine oral suspension, you should check to see if you have any of the specific batches at home. The batch number and expiry date can be found on the bottle and/or dispensing label. If you are unsure or unable to locate the batch number and expiry date, please contact your pharmacist for further advice.

Patients should be aware of the symptoms of overdose such as extreme drowsiness, vomiting, dizziness or confusion, slow or shallow breathing. If they experience any of these symptoms, then they should seek immediate medical assistance or visit the nearest accident and emergency centre.

Patients are advised to not stop taking their medication until they have spoken to their doctor. This is because suddenly stopping your medication also carries risks of severe side effects.

Your pharmacist, GP/doctor, or other healthcare professional will contact you as soon as possible to consider review of your treatment and to discuss any potential side effects experienced and ongoing monitoring. They will also advise on switching to an alternative treatment. Patients who have taken the affected batches previously may also be contacted for a review.

Any patient that may be worried that they have taken an affected batch can contact their healthcare professional to discuss any questions they may have. Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Additional information:

For more information, please contact Eaststone Limited on +44(0)800 678 3102 (Select Option 1) or email specials@eaststone.co.uk. For medical information queries, please contact Eaststone Limited on +44(0)800 678 3102 (Select Option 3) or email umar.ahmed@eaststone.co.uk

Reference Information:

1. Class 1 Medicines Recall Notification – Click Here

Defective Medicines Report Centre / Medicines and Healthcare products Regulatory Agency
10 South Colonnade Canary Wharf London,
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk

Please check website www.gov.uk/drug-device-alerts for when actions should be ceased or advice to check for date restriction are lifted.