MEDICINES RECALL

CLASS 2 MEDICINES RECALL, EL(26)A/43

Action within 48 hours

Issued 26 October 2026

Distribute to Patient/Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Xeal Pharma

MEDICINE DETAILS

Clopidogrel Oral Solution, Clopidogrel Oral Suspension

Unlicensed medicine (MS 46688)

Active Ingredient: clopidogrel hydrogen sulfate

SNOMED code: N/A

GTIN: N/A

AFFECTED LOT BATCH NUMBERS

For a list of defected batches, see Annex 1

Background

Xeal Pharma have informed MHRA that all strengths of their Clopidogrel Oral Suspension and Clopidogrel Oral Solution products contain less than the labelled amount of clopidogrel. Due to a formulation error, the impacted batches contain 76% of the required amount of clopidogrel. All batches produced prior to this notification are affected. Please note this is a Class 2 Patient, Pharmacy and Wholesaler level recall.

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.

Based on the risk assessment by Xeal Pharma, patient harm is not anticipated in patients receiving the affected product for long-term preventative treatment. However, patients would not receive the full, prescribed dose.

1. Pharmacists should identify and immediately contact all patients who have been dispensed these batches and ask them to confirm if they have remaining stock within their possession. If batch traceability information is not available, all patients dispensed this product from 20 July 2026 should be contacted. Patients should be informed that the product contained a lower dose than prescribed and patients and carers should be reminded that suddenly stopping this medicine may cause serious thrombotic events. If the pharmacist identifies any patients with an impacted product, they should contact the patient's GP or prescriber and discuss ongoing treatment for the patient. As patients may require monitoring, other clinicians and healthcare professionals may need to be involved.

2. Prescribers, clinicians, and other healthcare professionals involved in the prescribing/monitoring of patients who are using Clopidogrel Oral Solution or Suspension should contact their patients and/or carers directly to ensure that their treatment is reviewed.

Healthcare professionals should be aware that there are no licensed clopidogrel oral suspension/solutions available. Patients with impacted batches may require a dose correction, alternative licensed formulations or a different treatment option.

Xeal Pharma have confirmed that all future stock will be manufactured with the correct strength and calculations applied.

Advice for Patients:

Never stop taking medicines such as clopidogrel without medical advice. Suddenly stopping clopidogrel may cause serious thrombotic events.

Your GP, specialist, pharmacist, or other healthcare professional will contact you to, where required, make sure you get a new prescription for an alternative product. Once you have a replacement, you should return the impacted product to your pharmacy as part of the recall. You can contact your healthcare professional directly if you are worried, but you should keep taking your medicine as advised until you get an alternative.

No reports of patient harm have been received regarding this issue and the recall is being undertaken out of an abundance of caution. 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 all enquiries and information on this product, please email contact@xealpharma.co.uk, or telephone 0121 3090067.

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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