MEDICINES RECALL

CLASS 3 MEDICINES RECALL, EL(25)A/08

Action within 5 days

Issued 03 March 2025

Distribute to Pharmacy/Wholesaler Level Recall

MARKETING AUTHORISATION HOLDER

Accord Healthcare Ltd.

MEDICINE DETAILS

Azacitidine Powder for Suspension for Injection (100 mg/vial)

Licence: PLGB 20075/1408 Active Ingredient: Azacitidine

SNOMED code: 38237411000001103

GTIN: 05055565759622

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
P2206998	30/11/2025	1 vial pack	11/08/2023
P2300471	30/11/2025	1 vial pack	06/02/2024

MEDICINE DETAILS

Azacitidine Powder for Suspension for Injection (150 mg/vial)

Licence: PLGB 20075/1408
Active Ingredient: Azacitidine

SNOMED code: 41314711000001108

GTIN: 05055565784150

Page **1** of **3** DMRC Ref: 34527566 EL(25)A/08

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
P2302576	31/03/2026	1 vial pack	05/07/2024

Background

Accord Healthcare Limited is recalling the above batches of Azacitidine Powder for Suspension for Injection (100 mg/vial) & Azacitidine Powder for Suspension for Injection (150 mg/vial) as a precautionary measure due to out of specification results for Azacitidine related compound C impurity during stability testing. This recall is at pharmacy and wholesaler level.

Advice for Healthcare Professionals:

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

Accord Healthcare Limited is recalling the above batches as a precautionary measure, no adverse reactions have been reported with these batches to date.

Advice for Patients:

Patients are not required to take any action. This product is administered by healthcare professionals only.

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 medical information enquiries please contact Accord-UK Ltd Medical Information Department on 01271 385257 or email medinfo@accord-healthcare.com

For stock control enquiries please contact Accord-UK Ltd Customer Services Team on 0800 373573

Page **2** of **3** DMRC Ref: 34527566 EL(25)A/08

MEDICINES NOTIFICATION

Recipients of this Medicines Notification 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

DMRC@mhra.gov.uk

Page **3** of **3** DMRC Ref: 34527566 EL(25)A/08