Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler/Importer Level Recall

Date: 30 August 2022 EL (22)A/37 Our Ref: MDR 160-08/22

Dear Healthcare Professional,

Hikma Pharmaceuticals USA Inc

Lorazepam 2mg/ml Injection — Unlicensed medicine

Batch Number	Expiry Date	Pack Size	First Distributed
070084	31 July 2023	25 x 1ml	17 August 2020
070126	31 July 2023	25 x 1ml	17 August 2020
080060	31 July 2023	25 x 1ml	17 August 2020
080091	31 July 2023	25 x 1ml	17 August 2020

Lorazepam 4mg/ml Injection — Unlicensed medicine

Batch Number	Expiry Date	Pack Size	First Distributed
070096	31 July 2023	25 x 1ml	17 August 2020

Active Pharmaceutical Ingredient: lorazepam

Brief description of the problem
Hikma Pharmaceuticals USA Inc are recalling the above batches due to an out of specification result with related substances during testing for retain samples. This unlicensed medicine has been imported into the U.K. to meet the special need of individual patients.

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 are not required to take any action at this time. This product is administered by healthcare professionals only. If you have concerns about this notification, please contact your healthcare professional.

Further Information
For more information or medical enquiries, please contact pv@hikma.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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