



# MEDICINES RECALL

## CLASS 2 MEDICINES RECALL

Action Within 48 Hours  
Pharmacy/Wholesaler Level Recall

Date: 25 August 2021

EL (21)A/20

Our Ref: MDR 246-08/21

Dear Healthcare Professional,

### Rosemont Pharmaceuticals Limited

**Metformin Hydrochloride 500mg/5ml Oral Solution**

**PL 00427/0139**

Batch Number	Expiry Date	Pack Size	First Distributed
OLL0018	Nov 2021	150ml	December 2020

Active Pharmaceutical Ingredient: metformin hydrochloride

#### Brief description of the problem

Rosemont Pharmaceuticals Limited is recalling all unexpired stock of the above product from pharmacies and wholesalers as a precautionary measure due to the identification level of an impurity above the acceptable limit. Following routine monitoring, the impurity, N-nitrosodimethylamine (NDMA) which has genotoxic and carcinogenic potential, has been observed at a level above the acceptable limit.

#### 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.

Patients should be advised not to stop any treatments without consulting their relevant healthcare professional. The risks of suddenly stopping medication for type 2 diabetes is higher than the potential risk presented by the impurity.

#### Further Information

For stock control enquiries please contact: [Customerservices@rosemontpharma.com](mailto:Customerservices@rosemontpharma.com)

For medical information enquiries please contact: [pharmacovigilance@rosemontpharma.com](mailto:pharmacovigilance@rosemontpharma.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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