

**MEDICINES RECALL
CLASS 2 MEDICINES RECALL
Action Within 48 Hours
Pharmacy/Wholesaler Level Recall**

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

For medical information enquiries please contact:

pharmacovigilance@rosemontpharma.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

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Telephone No. 028 9536 0333

25th August 2021