

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy/Wholesaler Level

Dear Healthcare Professional

Rosemont Pharmaceuticals Ltd.

Atorvastatin 4mg/ml Oral Suspension

PL 00427/0256

Batch No	Expiry Date	Pack Size	First Distributed
ATV21001	Apr-2024	150 ml	28-Apr-2022
ATV21002	Apr-2024	150 ml	13-Jul-2022

Active Pharmaceutical Ingredient: Atorvastatin

Sildenafil 10mg/ml Oral Suspension

PL 00427/0258

Batch No	Expiry Date	Pack Size	First Distributed
SLD22001	Mar-2025	122 ml	Not yet distributed
SLD22002	Apr-2025	122 ml	22-Jun-2022

Active Pharmaceutical Ingredient: Sildenafil

Brief description of the problem:

Rosemont Pharmaceuticals Ltd. has made the MHRA aware that the expiry dates stamped on the base of the bottle are incorrect for the above 2 batches of Atorvastatin 4mg/ml Oral Suspension (indicated for hypercholesterolaemia and prevention of cardiovascular disease) and 2 batches of Sildenafil 10mg/ml Oral Suspension (indicated for pulmonary arterial hypertension). The correct expiry dates (as stated in the above table) are printed on the bottle label and on the outer carton. All other product details are correct, including the serial numbers and batch numbers.



Advice for healthcare professionals:

There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals should advise patients of the issue when dispensing these products. The products can be used until the expiry date printed on the bottle label and the outer carton. The expiry date stamped on the base of the bottle should be ignored. No other batches of Atorvastatin 4mg/ml Oral Suspension or Sildenafil 10mg/ml Oral Suspension marketed by Rosemont Pharmaceuticals are affected by this discrepancy.

Advice for patients:

Patients should note that the expiry date printed on the base of the bottle for these products is incorrect and should be ignored. There are no concerns about the safety or quality of the medicine. The expiry date is correct on the bottle label and the outer carton (box). Patients should use these products until the expiry date on the bottle label and outer carton. If a patient has any concerns, they should contact their pharmacist.

Further Information:

For further information please contact: pharmacovigilance@rosemontpharma.com

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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TO ALL CHEMISTS, DOCTORS ON THE LISTS

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2 Franklin Street
BELFAST
BT2 8DQ

Telephone No.

028 9536 0333

14th September 2022

Pharmaceutical website: <http://www.hscbusiness.hscni.net>