



MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 Days
Pharmacy/Wholesaler Level Recall

Date: 21 March 2023

EL (23)A/11

Our Ref: MDR 066-03/23

Dear Healthcare Professional,

Rosemont Pharmaceuticals Limited

Sildenafil 10mg/ml Oral Suspension

PL 00427/0258

SNOMED Code 40639911000001103

Batch Number	Expiry Date	Pack Size	First Distributed
SLD22002	April 2025	122ml	June 2022

Active Pharmaceutical Ingredient: Sildenafil (as Citrate)

Brief description of the problem

Rosemont Pharmaceuticals Limited has informed the MHRA that the Press In Bottle Adaptor (PIBA) supplied with the pack (carton) in the batch listed above is too wide to fit the neck of the medicine bottle.

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.

There is no risk to product quality as a result of this issue, and the affected batch is being recalled as a precautionary measure. Rosemont Pharmaceuticals Limited has confirmed that no other batches will be released with the incorrect PIBA and that the majority of the impacted packs have been distributed to hospitals (secondary care) where the doses will be administered under the supervision of a healthcare professional. A small number of packs have been dispensed by primary care teams, therefore specific advice is included below for patients (and healthcare professionals) who have been supplied with these packs. Healthcare professionals should note that the PIBA is an aid to dispensing and the oral suspension can be administered accurately using the syringe without the PIBA.

Advice for patients

The MHRA has been made aware of an issue where the Press In Bottle Adaptor (PIBA) supplied with the pack (carton) is too wide to fit the neck of the medicine bottle. This means that the PIBA cannot be used when trying to obtain a dose with the syringe provide. The PIBA is an aid to dispensing and the oral suspension can be administered accurately using the syringe without the PIBA.

No further action is required by patients as this is a Pharmacy and Wholesaler level recall. Patients should continue to take medicines from the impacted batch as prescribed by your healthcare professional. However, if there are any concerns with regards to using the syringe, your pharmacist will be available to provide further information and guidance.



Medicines & Healthcare products Regulatory Agency

The majority of the impacted packs will be administered under the supervision of a healthcare professional. Patients who are self-dosing should discard the PIBA and use the 2ml oral syringe supplied with the medication to obtain the required dose directly from the medicine bottle following the instructions below:

- Keeping the bottle upright, insert the 2ml oral syringe supplied into the bottle ensuring the tip of the syringe goes below the level of the liquid.
- Fill the syringe with a small amount of suspension by pulling the piston up whilst maintaining the tip of the syringe below the level of the liquid, then push the piston down in order to remove any possible bubble.
- Pull the piston upward to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor.
- Remove the syringe from the bottle.
- Close the bottle with the plastic screw cap.
- Empty the contents of the syringe into your mouth.
- After dosing, wash the syringe with water only.

As for all medicines, if you experience any adverse reactions, you should contact your doctor immediately. You can also report suspected adverse reactions via the MHRA [Yellow Card scheme](#).

Further Information

For more information, medical information queries or replacement PIBA enquiries, please contact: pharmacovigilance@rosemontpharma.com. For stock control queries, please contact: customerservices@rosemontpharma.com.

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

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