



MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 Days
Pharmacy/Wholesaler Level Recall

Date: 03 July 2023

EL (23)A/21

Our Ref: MDR 102-06/23

Dear Healthcare Professional,

Strandhaven Limited T/A Somex Pharma

Sildenafil 100mg Film-coated Tablets

PL 15764/0043

SNOMED Code: 326715008

Batch No	Expiry Date	Pack Size	First Distributed
ET22028	02/2025	4 tablets*	16.01.2023

* Mislabeled packs indicate 8 tablets

Active Pharmaceutical Ingredient: Sildenafil Citrate

Brief description of the problem

Strandhaven Limited T/A Somex Pharma has informed the MHRA that the pack size on some cartons of the batch in this notification state 8 tablets instead of 4 tablets. This is an error due to cartons being mixed at the printers. All cartons with batch number ET22028 contain one blister strip of 4 tablets regardless of whether it states 8 tablets or 4 tablets on the pack.

Only the batch listed in this notification is affected. Due to the low number of complaints received, only the packs labelled as containing 8 tablets are being recalled at this time. The batch is comprised of 60340 packs, to date 195 packs have been found to be mislabelled.

The quality and safety of the tablets is not impacted and therefore this is not a patient level recall.

Advice for healthcare professionals

Strandhaven Limited T/A Somex Pharma ask that healthcare professionals stop supplying and quarantine any stock with this batch number that is labelled as containing 8 tablets. Return these packs through your approved process.

The packs labelled as 4 tablets, can be dispensed as normal. The quality and safety of the tablets is not impacted and therefore this is not a patient level recall.

For Patients that were already prescribed 8 tablets and have received one pack of this batch (the patient will have received only 4 tablets). Should the patient raise a complaint:

- For prescriptions written within the last 6 months, check the pack being returned by the patient and the dispensing record (Summary Care Record may be checked with the patient's consent) to confirm there was an error and dispense a further 4 tablets. Following advice from the Department of Health and Social Care, this is considered a correction to the original prescription



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and a further prescription would not be necessary. Follow your company's returns procedure through your wholesaler to arrange a credit note or contact SomexPharma to arrange the supply of the additional 4 tablets or credit note (see Further Information section) for further details.

Advice for patients

Strandhaven Limited T/A Somex Pharma have informed MHRA of an error related to the quantity of tablets printed on the pack in one batch of Sildenafil 100mg Film-coated Tablets. The carton may indicate that the pack contains 8 tablets, however in all cases the cartons contain 4 tablets. You will find one blister strip of 4 tablets inside each box, which is correct. If you have received a pack with this batch number, please consider the following information:

- The quality and safety of the tablets is not impacted and therefore you should continue to take medicines from this batch as prescribed by your healthcare professional;
- If you have been prescribed 4 tablets and the pharmacist has dispensed a pack from this batch that reads 8 tablets – this is a typographical error on the carton. You will correctly receive 4 tablets as prescribed. If in doubt you can double check with your pharmacist;
- If you have been prescribed 8 tablets and the pack is labelled as containing 8 tablets but only contains 4 tablets, please contact your pharmacist. If the prescription was written within 6 months, the pharmacist will arrange for the dispensing of the missing 4 tablets. Alternatively, contact Strandhaven Limited T/A Somex Pharma (see Further information for contact details).

If you would like to discuss this issue further, please contact Strandhaven Limited T/A Somex Pharma (see Further information for details) to address your concerns.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For medical information enquiries please contact email: regulatory@somexpharma.com, Tel: 020 8590 9399, choose option 3 or 4.

For stock control enquiries please contact email: regulatory@somexpharma.com, Tel: 020 8590 9399, choose option 3 or 4.

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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