

Batch Recall

Fluzac 20mg Capsules, PA0711/110/001

Batch No.	Expiry Date	Batch No.	Expiry Date
KD6260	09/2024	KU7858	05/2025
KL1914	01/2025	KV3140	05/2025
KR9080	03/2025	KV3141	05/2025
KR9082	03/2025	KZ6820	05/2025
KU7859	03/2025	KZ6821	07/2025

1st March 2024

Dear Pharmacist,

We wish to advise you that the above listed batches of Fluzac 20mg Capsules, PA0711/110/001, are being recalled as a precautionary measure.

This recall is going to pharmacy level. The action has been agreed with the Health Products Regulatory Authority.

The precautionary recall is due to the presence of the nitrosamine impurity N-nitroso-fluoxetine which was detected at levels above the acceptable regulatory limit in the listed batches.

Please perform the following actions:

1. Check your current inventory and immediately quarantine any units of the above listed batches which you have in your possession. For hospital pharmacies, this includes stock on wards, in clinics and any at other relevant locations within your hospital.
2. If you have supplied units from the above listed batches to any other pharmacy, clinic or other such establishment, forward a copy of this recall letter to them, and request they quarantine and return any unused units to you.
3. Return all quarantined units to your wholesaler. Credit will be issued for stock returned within two weeks.

Unaffected stock of Fluzac 20mg Capsules is currently available to order.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Anne Daly at telephone number (027) 50077.

Yours sincerely,



Anne Daly, Quality Manager,
(027) 50077



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Directors: B. Wagner - Halswick, Managing (German) • S. Zilg (German) • M. Kocher (German) • M. Weber (German)
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