

Medicine Quality Alert: Class III Recall of Famcal tablets, Batch No FDF1AD3B

Sai Pharmaceuticals (Kenya) Limited has initiated an urgent recall of batch **FDF1AD3B** for Famcal tablets (Calcium citrate malate 250mg; cholecalciferol 100 i.u).

From: Pharmacy and Poisons Board
Published: 14th December 2022

Recall Reference Number: REC/2022/11

Recall Classification: Class III

Recall Level: Wholesale/Distributor Level

Manufacturer: Indoco Remedies Limited, India

Local Technical Representative: Sai Pharmaceuticals (Kenya) Limited

Product name: Famcal tablets

Active Pharmaceutical Ingredient: Calcium citrate malate 250mg; cholecalciferol 100 i.u

Batch Number	Date of Manufacture	Date of expiry	Pack Size
FDF1AD3B	01.2022	12.2023	30's

Brief description of the problem

Sai Pharmaceuticals (Kenya) Limited is recalling batch FDF1AD3B Famcal tablets (Calcium citrate malate 250mg; cholecalciferol 100 i.u) due to out-of-specification results on assay test of cholecalciferol during the review of stability results.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing, or use of batch **FDF1AD3B** and immediately return to the supplier.

Action for patients and caregivers

No further action is required by patients as this is a Wholesaler/Distributor level recall. The patients should continue taking other batches of the product other than the impacted batches and as prescribed by the healthcare professional.

Further Information

For any Famcal stock enquiries please contact Sai Pharmaceuticals (Kenya) Limited via email at Head-regulatory@saipharm.com or via telephone at +254 731 952 330

You are encouraged to promptly report any case/s of suspected substandard and falsified product or adverse reactions or insufficient control of symptoms to the nearest healthcare facility or the Pharmacy and Poisons Board through the following channels:

- <https://pv.pharmacyboardkenya.org/users/mpublic>
- USSD code at *271#
- Email pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further enquiries contact the post-marketing surveillance unit at the Pharmacy and Poisons Board via email at pms@pppb.go.ke