Medicine Quality Alert: Class II Recall of Dopamac (Methyldopa 250 mg) Batch Number HMX20007A, HMX20008A, and HMX20009A

The Pharmacy and Poisons Board has issued a mandatory recall of Dopamac (Methyldopa 250 mg) batches; ***HMX20007A; HMX20008A & HMX20009A*** manufactured by Macleods Pharmaceuticals Ltd.

From: Pharmacy and Poisons Board
Published: 25th April 2023

Recall Reference Number: REC/2023/004
Recall Classification: Class II
Recall Level: Retail/Facility level
Manufacturer: Macleods Pharmaceuticals Ltd
Local Technical Representative: Sai Pharmaceuticals Limited, Kenya
Product name: Dopamac
Active Pharmaceutical Ingredient: Methyldopa 250 mg
Affected Counties: All

Affected Batches

Batch Number	Date of Manufacture	Date of expiry	Pack Size
HMX20007A	01/10/2020	30/09/2023	100's
HMX20008A	01/10/2020	30/09/2023	100's
HMX20009A	01/10/2020	30/09/2023	100's

Brief description of the problem
The product is being recalled following several market complaints on quality defects of the impacted batches. The nature of the complaints is cracking of tablet coating and color change. On further investigations, reports noted the color change and cracking of the tablet coat, indicating discrepancies from the product's intended physical characteristics.

Action for healthcare professionals
You are advised to stop supplying the above batches and immediately quarantine all remaining stocks. The company Sai Pharmaceuticals Limited, will contact retail/hospital pharmacies directly to arrange the return of the products.

Action for patients and carers
No further action is required by patients as this is a Retail/hospital Pharmacy level recall. Patients should continue taking other batches of the product other than the impacted batches and as prescribed by the healthcare professional.

Further Information
For stock enquiries please contact Sai Pharmaceuticals Limited be email at: head-regulatory@saipharm.com, sales@saipharm.com, info@saipharm.com, or via telephone at +254-20-4454301/2/3, +254-733-741-911, +254-721-243-322

You are advised to promptly report any cases of adverse events and suspected substandard and falsified products to the nearest healthcare facility or 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 information please contact the post-marketing surveillance unit at the Pharmacy and Poisons Board by email: pms@ppb.go.ke