



Quality Medicines for Malawi

PUBLIC SAFETY ALERT NOTICE

RECALL OF SPECIFIED BATCHES OF NIFEDIPINE 10MG TABLETS, LEVODOPA/CARBIDOPA 100/25MG TABLETS & LEVODOPA/CARBIDOPA 250/25MG TABLETS MANUFACTURED BY REMEDICA LTD, CYPRUS

The Pharmacy and Medicines Regulatory Authority (PMRA) is informing healthcare professionals, licensed pharmaceutical importers, wholesalers, retail pharmacies, healthcare facilities, and the general public that it has been made aware of an official regulatory recall notice issued by the Medicines Control Authority of Zimbabwe (MCAZ) via Circular No. 22 of 2026, dated 7th September 2026.

The MCAZ notice announces a Class II recall up to retail level for specified batches of Nifedipine 10mg Tablets, Levodopa/ Carbidopa 100mg/25mg Tablets and Levodopa/ Carbidopa 250mg/25mg Tablets manufactured by Remedica Ltd of Cyprus. The recall follows confirmed out-of- specification results during ongoing stability testing of the products.

The batches affected by the recall in Zimbabwe are as follows:

Product	Affected batch numbers	Nature of the quality defect
Nifedipine 10 mg tablets	112033 117367	Out-of-specification dissolution profile, affecting predominantly the early stages of dissolution.
Levodopa/Carbidopa 100 mg/25 mg tablets	97261 102600 102603 107232	Change in appearance, with the tablets changing from yellow to dark yellow or brownish at the end of shelf life.
Levodopa/Carbidopa 250 mg/25 mg tablets	99671 102751 102752	Change in appearance, from blue to yellowish green, together with recurring out-of-specification results associated with a decrease in the carbidopa assay.

PMRA wishes to assure the public that neither Nifedipine 10 mg tablets nor Levodopa/Carbidopa tablets manufactured by Remedica Ltd are registered for use in

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Malawi. The Authority has, therefore, not authorised any person or establishment to import, distribute, sell, or supply these products in the country, and no legitimate supply of the affected batches is expected on the Malawian market.

Should any of the affected products be found to have been illegally imported into Malawi, they would be on the market in contravention of the PMRA Act (2019), and their quality, safety, and effectiveness cannot be guaranteed.

Medicines that fail dissolution or assay specifications may not release the correct amount of active ingredient, which can result in treatment failure.

All licensed pharmaceutical wholesalers, pharmacies, drug stores, and healthcare facilities are directed to:

- Inspect their stock immediately for the products and batch numbers listed above.
- Immediately stop the sale, distribution, and dispensing of any such stock, if found.
- Quarantine the affected stock, clearly labelled and separated from usable stock, pending further instructions from PMRA.
- Report the discovery of any such stock to PMRA without delay, stating the quantity held, the batch numbers, and the source of supply.

Members of the public are advised to:

- Check any nifedipine or levodopa/carbidopa medicines in their possession against the product names and batch numbers listed above. The batch number is usually printed on the blister strip, the bottle label, or the outer carton or container.
- If in possession of any of the affected batches, stop using the product immediately and return it to the pharmacy or health facility where it was obtained.
- Purchase medicines only from pharmacies, and health facilities that are licensed by PMRA.

The Authority further reminds pharmaceutical importers, retailers, healthcare workers, and consumers to always be vigilant and report any suspected poor-quality medicines or adverse drug reactions to the nearest healthcare facility and to the PMRA via Medsafe 360 by dialing *360# for free on TNM and Airtel networks.

For more information and/ or clarification regarding this safety alert notice please contact PMRA on +265 899 567 365 or email at info@pmra.mw.


Charles Chimpenya
DIRECTOR GENERAL
15th September, 2026



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