



RWANDA FDA

Rwanda Food and Drugs Authority

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www.rwandafda.gov.rw

Kigali on; 28/04/2021

Ref N°: DIS/1441/FDA/2021

District Pharmacies (All)

District Hospitals (All)

Referral Hospitals (All)

Central medical stores (All)

Pharmaceutical Wholesalers (All)

Importers (All)

Retail Pharmacies (All)

Public and private Health facilities (All)

Title: Recall for all batches of Unibrol (Aminosidine Sulphate USP 250mg) manufactured by UNIVERSAL Corporation Ltd, Kenya.

Reference is made to the **Law N° 003/2018 of 09/02/2018** establishing Rwanda Food and Drugs Authority especially in its article 8 paragraph 2 and 13. Reference is made to the call for quarantine issued by Rwanda FDA on 12th January 2021 for all batches of Unibrol (Aminosidine Sulphate) USP 250mg tablets manufactured by UNIVERSAL Corporation Ltd, Kenya.

Reference is also made to the letter with Ref No.UCL/QA/RM/2021/02/090 from Universal Corporation Limited addressed to Pharmacy and Wholesalers in Rwanda about Unibrol 250mg market withdrawal.

Further reference is made to the deep investigation and Laboratory quality control tests performed by Rwanda FDA on all batches of Unibrol (Aminosidine Sulphate) USP 250mg tablets which confirmed that the medicine is of poor quality; some tablets on the same blister changed colour from white to yellow.

It is with this background that Rwanda FDA recalls from the Rwandan market all batches of UNIBROL (Aminosidine Sulphate) USP 250mg tablet manufactured by UNIVERSAL CORPORATION LTD, Club road, Plot No.13777, Kikuyu, Kenya.

Action to be taken

- Rwanda Food and Drug Authority instructs all importers, central medical stores, Wholesalers, RMS Ltd branches, retailers, Public and Private Health Facilities to return the quarantined Unibrol tablet (Aminosidine Sulphate USP 250mg) to the supplier for proper management
- The importers and Suppliers of Unibrol (Aminosidine Sulphate USP 250mg) are requested to report to Rwanda FDA within 10 working days the quantities imported, quantities distributed, quantities returned and final stock on hand
- Rwanda FDA will communicate officially when importation of Aminosidine Sulphate USP 250mg manufactured by UNIVERSAL Corporation Ltd, Clubroad, Plot No.13777, Kikuyu, Kenya will be permitted. This will be after the manufacturer completes implementation of the Corrective and Preventive actions
- **Note:** For more information or to report any suspected poor quality products please call **0789193529** or **9707** or send email to: pv_sm@rwandafda.gov.rw

You will find pictures for this medicine and the quality issue as attachment

Sincerely,

Dr. Charles KARANGWA
Ag. Director General

The logo of the Rwanda Food and Drug Authority (FDA) is centered in the background. It features a stylized caduceus (a staff with two snakes) in light blue and green, set against a yellow sunburst. The entire emblem is framed by a circular wreath of golden-brown leaves.

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