



RWANDA FDA
Rwanda Food and Drugs Authority

P.O. Box 84 Kigali

info@rwandafda.gov.rw

www.rwandafda.gov.rw

Kigali, 12/01/2021

Ref N°: DIS/ 046 /FDA/2021

RMS Branches (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)
Health Insurances (All)

Title: Call for quarantine of All batches of Unibrol (Aminosidine Sulphate) USP 250mg tablets 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;

Further reference is made to the previous recall letter with Ref. N°: DIS/2887/FDA/2020 dated 29th November 2020 for two (2) batches N° **5806898** and **5806675** of Unibrol (Aminosidine Sulphate) USP 250mg tablets manufactured by UNIVERSAL Corporation Ltd, Kenya and taking into consideration the results of laboratory tests performed by Rwanda FDA;

Despite the investigation report, corrective actions and preventive actions (CAPA) submitted by the manufacturer on the above mentioned batches, similar quality complaints were reported to Rwanda FDA by different retail pharmacies and clients on other batches of UNIBROL (Aminosidine Sulphate) USP 250mg tablet where some tablets on the same blister changed color from white to yellow.

It is on this background that all batches of UNIBROL (Aminosidine Sulphate) USP 250mg tablet manufactured by UNIVERSAL CORPORATION LTD, Club road, Plot No.13777, Kikuyu, Kenya are called for quarantine while Rwanda FDA conducts deep investigation targeting all batches of Unibrol (Aminosidine Sulphate) USP 250 tablets mg circulating on the Rwandan market.

Action to be taken

- Rwanda Food and Drugs Authority instructs all importers, central medical stores, wholesalers, District Pharmacies, retailers, Public and Private Health facilities in possession of Unibrol (Aminosidine Sulphate) USP 250mg tablets to quarantine all quantities in their stores until the investigation will be concluded.
- The importation of any batch of UNIBROL (Aminosidine Sulphate USP 250mg) manufactured by UNIVERSAL CORPORATION LTD, Club road, Plot No.13777, Kikuyu, Kenya is suspended until further notice.

Note: For more information or to report any suspected poor-quality products please call **0789 19 35 29** or send email to: pv_sm@rwandafda.gov.rw

You will find pictures for the medicine showing the quality issue as attachment; normally unibrol tablets are white in color.

Sincerely,

Dr. Charles KARANGWA
Ag. Director General



RWANDA FDA
Rwanda Food and Drugs Authority

PHOTOS SHOWING UNIBROL 250MG TABLETS



RFDA FDA
Rwanda Food and Drugs Authority