



Rwanda Food and Drugs Authority

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QMS N°: FDISM/PVSM/FMT/034

Revision No: 0

Effective Date: 31/03/2023

RECALL NOTIFICATION

Kigali on 29 / 12 /2023

Ref. No.: FDISM/PVSM/...../FDA/2023

Central medical stores (All)
RMS branches (All)
Pharmaceutical Wholesalers (All)
Importers of medical products (All)
Retail Pharmacies (All)
Public and private Health facilities (All)
Health professionals (All)

Title: Recall of batches of Fluconazole 200mg tablets manufactured by Universal Corporation Ltd/Kikuyu, Kenya

Type of the recall: Voluntary

Class of the recall: Class II

Recall level: Retail / Facility level

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 also made to regulation No.: CBD/TRG/019 Rev_1 governing the Recall, Treatment and Disposal of Unfit regulated products in its article 6

Reference is also made to the letter with ref. No UCL/PD/pp/2023/05/043 by Universal Corporation Ltd notifying the recall of Fluconazole 200mg due to discoloration of tablets. Further reference is made to the investigation performed by Rwanda FDA which confirmed that some incriminated batches were imported into Rwanda;

It is with this background that Rwanda FDA recalls from the Rwandan market the following batches of Fluconazole 200mg tablets:

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DESCRIPTION	BATCH	Expiry Date	Manufacturer	Quality issue
Fluconazole 200mg tablets	5810315	31/01/2025	Universal Corporation Ltd	The pink tablets displayed white discoloration
Fluconazole 200mg tablets	5810316	31/01/2025	Universal Corporation Ltd	The pink tablets displayed white discoloration
Fluconazole 200mg tablets	5811390	31/08/2025	Universal Corporation Ltd	The pink tablets displayed white discoloration
Fluconazole 200mg tablets	5810022	31/08/2025	Universal Corporation Ltd	The pink tablets displayed white discoloration

Action to be taken

- Rwanda FDA instructs all importers, central medical stores, wholesalers, RMS branches, retailers, Public and Private Health Facilities to stop the distribution of the above-mentioned batches of fluconazole 200mg tablets and return them to their suppliers for proper management.
- The importers and suppliers of above mentioned-batches of fluconazole 200mg tablets manufactured are requested to report to Rwanda FDA within 10 days from the date of publication of this recall, the quantities imported, quantities distributed, quantities returned and final stock on hands.

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

Sincerely,

E. Bienvenu
29/12/2023

Prof. Emile BIENVENU
Director General



PICTURE OF RECALLED PRODUCT



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