



RWANDA FDA
Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

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www.rwandafda.gov.rw

Kigali on; 11/06/2021
Ref N°: DIS/2100/FDA/2021

RMS Ltd (All Branches)
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 Nystatin Oral Suspension BP 100, 0000I.U/ml manufactured by DAWA Limited, Nairobi/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 also made to Call for quarantine Ref. N°: DIS/1856/FDA/2021 issued by Rwanda FDA on 25th May 2021 for batch No 2006004 of Nystatin Oral Suspension BP 100, 0000I.U/ml manufactured by DAWA Limited, Nairobi/Kenya;

Further reference is made to the deep investigation and laboratory quality control tests performed by Rwanda FDA on the concerned batch which confirmed the formation of precipitate at the bottom of the container that do not readily dissolve at gentle shaking;

We regret to notify that the following batch were found with that quality issue and Rwanda FDA recalls it from the Rwandan market:

DESCRIPTION	BATCH	Mfg date	Exp date	Manufacturer
Nystatin oral suspension BP 100,000I.U/ml	2006004	06/2020	05/2022	DAWA Limited, Plot No.7879/8,Baba Dogo Rd,Ruaraka.P.O.Box 16633-00620,Nairobi,Kenya.

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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 stop the distribution and dispensing of the above mentioned batch and return it to their supplier for proper disposal.
- The importers and Suppliers of the above incriminated batch of Nystatin Oral Suspension BP 100, 0000I.U/ml are requested to report to Rwanda FDA within 10 working days the quantities imported, quantities distributed, quantities returned and final stock on hand.
- **Note:** For more information or to report any suspected poor quality products please call **0789193529** or call Toll free **9707** or send email to: pv_sm@rwandafda.gov.rw

The Authority takes into consideration every information from stakeholders to ensure safe and quality products.

Please find an attachment of the picture of the incriminated medicine being recalled

Sincerely,



Dr. Charles KARANGWA
Ag. Director General



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