



RWANDA FDA

Rwanda Food and Drugs Authority

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www.rwandafda.gov.rw

Kigali on 25/05/2021
Ref N°: DIS/ 1851 /FDA/2021

RMS branches (All)

District Hospitals (All)

Referral Hospitals (All)

Pharmaceutical Wholesalers (All)

Importers (All)

Retail Pharmacies (All)

Public and private Health facilities (All)

Title: Recall for batch of Amoxicillin 250mg B.P capsules

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 spontaneous report received by the Authority on poor quality of Amoxicillin capsule BP 250mg with batch number MP18485A ,

Considering the investigation conducted by Rwanda FDA, where Amoxicillin capsule BP 250mg with batch number MP18485A was found with visible particles in the powder in the capsules,

The following mentioned batch of Amoxicillin capsules BP 250mg is recalled from the Rwandan market:

DESCRIPTION	BATCH	Mfg. date	Exp. date	Manufacturer
Amoxicillin capsules BP 250mg	MP18485A	-	09/2021	MILAN LABORATORIES (INDIA) PVT. LTD



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Action to be taken

- The importation of Amoxicillin capsules BP 250mg manufactured by MILAN LABORATORIES (INDIA) PVT. LTD is suspended until they comply with Rwanda FDA product registration requirements.
- Rwanda Food and Drugs Authority instructs all importers, central medical stores, wholesalers, District Pharmacies, retailers, Public and Private Health Facilities to stop the distribution of the above incriminated batch of Amoxicillin capsules BP 250mg and return them to the suppliers for suitable management.
- The importers and Suppliers of incriminated batch of Amoxicillin capsules BP 250mg 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 **0789 19 35 29** or send email to: pv_sm@rwandafda.gov.rw

Sincerely,



Dr. Charles KARANGWA
Ag. Director General

RWANDA FDA
Rwanda Food and Drugs Authority