



RWANDA FDA

Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

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Kigali on; 14/04/2021

RefN^o: DIS/ 1256/FDA/2021

District Pharmacies (All)

Referral Hospitals (All)

District Hospitals (All)

Central medical stores (All)

Pharmaceutical Wholesalers (All)

Importers (All)

Retail Pharmacies (All)

Re: Recall for a batch of Erythromycin Estolate Oral Suspension USP 125mg/5ml (AGOMYCIN)

Reference is made to the **Law N^o 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 the Laboratory quality control test report within the routine Post Marketing Surveillance activities;

Rwanda FDA recalls the following batch of Erythromycin Estolate Oral Suspension USP 125mg/5ml (AGOMYCIN) that was found out of specification for the content of Erythromycin Estolate, from the market;

DESCRIPTION	BATCH	Mfg date	Exp date	Manufacturer
Erythromycin Estolate Oral Suspension USP 125mg/5ml/AGOMYCIN Suspension	L96013	Nov.2019	Oct.2022	AGOG Pharma Limited, India

Action to be taken

- 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 Erythromycin Estolate Oral Suspension USP 125mg/5ml (AGOMYCIN) and return them to the suppliers for suitable management.
- The importers and Suppliers of the incriminated batch of Erythromycin Estolate Oral Suspension USP 125mg/5ml/AGOMYCIN 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 send email to: pv_sm@rwandafda.gov.rw

You will find pictures of the recalled medicine as attachment.

Sincerely,

Dr. Charles KARANGWA
Ag. Director General



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