



RWANDA FDA
Rwanda Food and Drugs Authority
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Kigali, 13 FEB 2020
Ref N° 260 /RwandaFDA/2020

District Pharmacy (All)
District Hospital (All)
Referral Hospital (All)
Wholesale pharmacy (All)
Importer (All)
Retail Pharmacy (All)

Title: Recall for Azithromycin Dry suspension 200 mg/5ml (ZEROCIN®)

Reference made to the spontaneous reports from clients, retail Pharmacies, wholesale pharmacies and further investigation conducted by Rwanda FDA where the powder of azithromycin was found with effect of powder caking which make reconstitution hard. We regret to notify that the following batches were found with that quality issue.

DESCRIPTION	BATCH	Mfg. Date	Exp. Date	Manufacturer
Azithromycin Dry suspension 200 mg/5ml (ZEROCIN®)	74346	05/2019	04/2021	Laboratory & Allied Ltd. Plot No.209/10349, Mombasa Road P.o.Box 42875, Nairobi, Kenya
Azithromycin Dry suspension 200 mg/5ml (ZEROCIN®)	74261	04/2019	03/2021	Laboratory & Allied Ltd. Plot No.209/10349, Mombasa Road P.o.Box 42875, Nairobi, Kenya

Action to be taken

Rwanda Food and Drugs Authority instructs all importers, central medical stores, wholesalers pharmacies, District Pharmacies, retail Pharmacies, Public and Private Health Facilities in possession of the above mentioned batches and clients to stop distribution, dispensing and administration of the above incriminated batches and return them to their suppliers

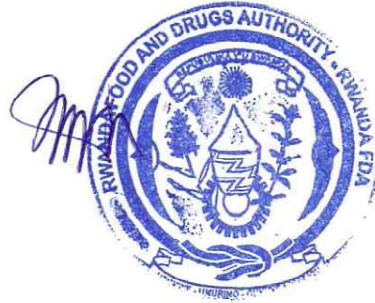
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Rwanda FDA instructs all importers to provide a report on quantities imported, distributed, returned and stock on hand within 5 calendar days.a

Note: Please find an attachment of the picture of the incriminated medicines being recalled.

Sincerely,

Dr. Charles KARANGWA
Ag. Director General



CC:

- **Hon. Minister of Health**
- **Hon. Minister of state in Charge of Primary Health care**
- **Director General of RBC**

ZEROCIN[®]

DRY SUSPENSION

Azithromycin Dry Suspension



POM

15ml

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ZEROCIN[®]
DRY SUSPENSION

Azithromycin Dry Suspension

Each 5ml of reconstituted suspension contains:

Azithromycin Ph Eur
equivalent to 200mg Azithromycin
anhydrous

Dosage:

As directed by the Physician.
Shake well before taking each dose.

Storage Conditions:

Store in dry place below 30°C.
Protect from light.

Keep all medicines out of reach of
children.

Replace cap securely.

Reg. No. : H2015/CTD3080/603

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