



**RWANDA FDA**  
Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

[info@rwandafda.gov.rw](mailto:info@rwandafda.gov.rw)

[www.rwandafda.gov.rw](http://www.rwandafda.gov.rw)

Kigali on: 25/05/2021  
Ref N°: DIS/ 1857 /FDA/2021

**RMS Ltd (All Branches)**  
**District Hospitals (All)**  
**Referral Hospitals (All)**  
**Pharmaceutical Wholesalers (All)**  
**Importers (All)**  
**Retail Pharmacies (All)**  
**Public and private Health facilities (All)**

**Title: Recall for a batch of Azithromycin dry suspension 200mg/5ml (ZEROCIN®)**

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 suspected poor quality reports from wholesale pharmacies and deep investigation and Laboratory quality control analysis that confirmed powder of azithromycin with an effect of powder caking which makes reconstitution hard,

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

No	DESCRIPTIONS	Batch Number	Expiry Date	Manufacturer
1	Azithromycin dry suspension 200mg/5ml (ZEROCIN®)	No: 75363	08/2021	Laboratory & Allied Ltd, Kenya

**Action to be taken**

- Rwanda Food and Drugs Authority instructs all importers, central medical stores,

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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 management.

- The importers and Suppliers of the above incriminated batch of Azithromycin dry suspension 200mg/5ml (ZEROCIN®) are requested to report to Rwanda FDA within 10 working days the quantities imported, quantities distributed, quantities returned and final stock on hand.
- The importation of Azithromycin dry suspension 200mg/5ml (ZEROCIN®) manufactured by Laboratory & Allied Ltd, Kenya is suspended until registration process with Rwanda FDA is completed and GMP inspection conducted.
- **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](mailto:pv_sm@rwandafda.gov.rw)

The authority takes into consideration all information from stakeholders to ensure safe and quality products are available for the Rwandan population

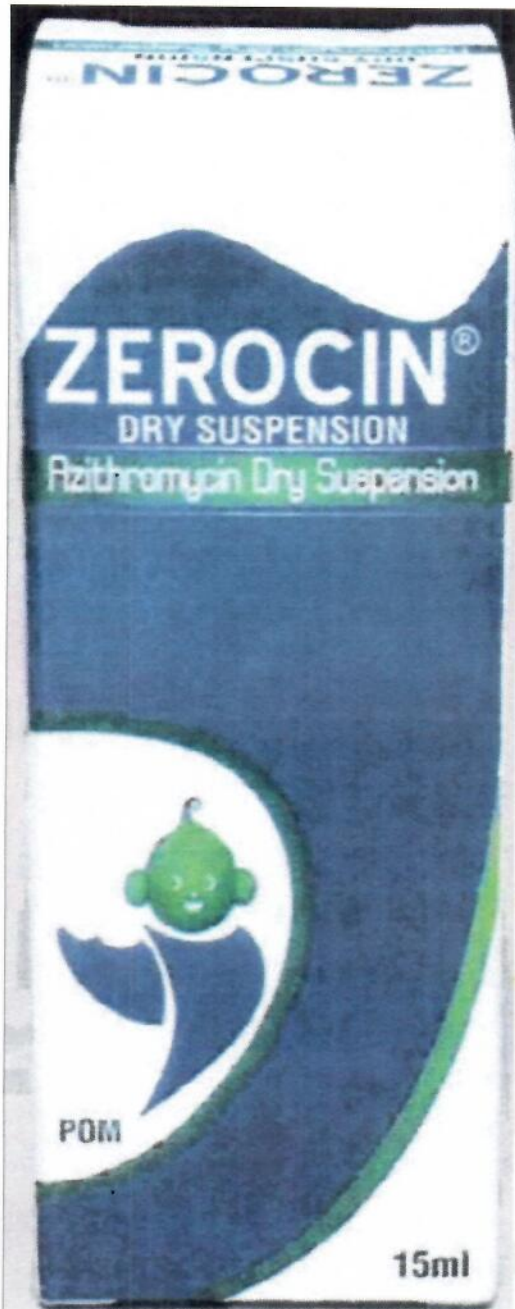
Please find an attachment of the picture of the incriminated medicine being recalled

Sincerely,

**Dr. Charles KARANGWA**  
**Ag. Director General**



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