



RWANDA FDA
Rwanda Food and Drugs Authority

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Kigali, 19-03-2020
Ref N° 496 /RwandaFDA/2020

District Pharmacies (All)
District Hospitals (All)
Referral Hospitals (All)
Central medical stores (All)
Wholesale pharmacy (All)
Importers (All)
Retail Pharmacies (All)

Title: Recall for batch of Entamizole®DS (Diloxanide Furoate/Metronidazole 500/400mg) tablets

Reference made to the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA especially in its article 8 paragraph 2, reference is also made to the spontaneous reports from retail Pharmacies, wholesale pharmacies, importers and investigation conducted by Rwanda FDA, it was found that Batch number and expiry dates on blisters were different from the one on outer package of Entamizole 500 mg DS tablets. This is an indication of suspected poor quality products. We regret to notify that the following batch was found with the above mentioned quality issue:

Description	Outer/ Inner Package	Batch/Lot	Mfg. date	Exp.date	Manufacturer
Entamizole®DS (Diloxanide Furoate/Metroni dazole 500/400mg)	Outer package	94965XV	11/2018	11/2021	Abbot Laboratories (Pakistan) Ltd., Landhi, Karachi.
	Blister	95532XV	Not mentioned	01/2022	

Action to be taken

Rwanda Food and Drug Authority instructs all importers, central medical stores, wholesalers, District Pharmacies, retailers, Public and Private Health Facilities in possession of the above incriminated products to stop the distribution of the above incriminated batch to return them to the suppliers for suitable management.

The importers and Suppliers of incriminated batch of Entamizole 500/400mg DS are requested to report to Rwanda FDA within 10 working days the quantities imported per product, quantities distributed, quantities returned and final stock on hand.

Sincerely,

Dr. Charles KARANGWA
Ag. Director General



CC:

- **Hon. Minister of Health**

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