



RWANDA FDA

Rwanda Food and Drugs Authority

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Kigali 14 MARS 2019

Ref N°/0310/Rwanda FDA/2019

District Pharmacies (All)
District Hospitals (All)
Referral Hospitals (All)
Pharmaceutical Wholesalers (All)
Retail Pharmacies (All)
Private clinics/ (All)

Title: Recall of Dexamethasone sodium injection 4mg/ml

The role of the Rwanda FDA is to protect the public health by disseminating information on quality and safety of products regulated under the law N° 003/2018 of 09/02/2018 to health professionals and other concerned organs. The Authority takes into considerations every information from Partners to ensure safe and quality products on our market.

Referring to the spontaneous reports from Health Facilities and wholesalers the product was found with incomplete labelling where the route of administration was not mentioned on the vial as required by registration guidelines for proper guidance of the health professionals, we regret to notify the following batches where found with incomplete labelling:

DESCRIPTION	BATCH	Mfg. Date	Exp. Date	Manufacturer
Dexamethasone 4mg/ml Sodium Injection	180468	04/2018	03/2021	JIANGXI XIERKANGTAI PHARMACETICAL CO. LTD/CHINA

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Action taken

Rwanda Food and Drug Authority instructs all wholesalers, District Pharmacies, retailers, Public and Private Health Facilities to stop the distribution and dispensing of the above incriminated batches of Dexamethasone 4mg/ml Sodium Injection and return them to suppliers for suitable disposal management.

Sincerely,



Dr. Charles KARANGWA
Ag. Director General of Rwanda FDA

CC:

- **Hon. Minister of Health**
- **Hon. Minister of State in Charge of Primary Health care**
- **Permanent Secretary/MOH**
- **D.G Rwanda Biomedical Center**



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