

Kigali, 12.1 FEB 2019  
Ref N° 0162 /Rwanda FDA/2019



**RWANDA FDA**  
Rwanda Food and Drugs Authority  
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District Pharmacy (All)  
District Hospital (All)  
Referral Hospital (All)  
Pharmaceutical Wholesalers (All)  
Retail Pharmacies (All)  
Private clinics/ (All)

**Title: Product recall (Hydralazine hydrochloride 20 mg/ml)**

The role of the Rwanda FDA is to protect the public health by regulating Food and Drugs and 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.

Referring to the notification from manufacturer (SWISS PARANTERALS LTD) where retained samples failed on-going stability studies after 6 months and the manufacturer requested the recall of the product below:

DESCRIPTION	BATCH	Mfg. Date	Exp. Date	Manufacturer
Hydralazine 20 mg/ml	SX-18275	July 2018	June 2020	SWISS PARANTERALS LTD GUJARAT/INDIA
Hydralazine 20 mg/ml	SX-18287	July 2018	June 2020	SWISS PARANTERALS LTD GUJARAT/INDIA

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### **Action to be 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 Hydralazine 20 mg/ml 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**
- **DG Clinical and Public Health Services**

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