



Kigali on 27/01/2023

Ref. N°: FDISM/PVSM/447/FDA/2023

RMS Ltd (All Branches)
Central medical stores (All)
Pharmaceutical Wholesalers (All)
Public and private Health facilities (All)
Importers (All)
Retail Pharmacies (All)
Health professionals (All)
General public

Title: Recall for some batches of Gastro-resistant Sodium valproate BP 500mg and 300 mg tablets manufactured by 4Care Lifescience Pvt Ltd/India

Type of the recall: Statutory

Class of the recall: Class III

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;

Reference is also made to the spontaneous reports suspecting the poor quality of Gastro-resistant Sodium valproate 500mg and 300 mg tablets manufactured by 4Care Lifescience Pvt Ltd; from different health facilities;

Further reference is made to deep investigations conducted by the Authority including sampling and laboratory quality control test analysis which confirmed that gastro-resistant sodium valproate 500mg and 300 mg tablets manufactured by 4Care Lifescience Pvt Ltd with the batch numbers mentioned below do not comply with quality standards. It is against this regard that the Authority recalls from the market the following batches of Gastro-resistant Sodium valproate with below descriptions:

DESCRIPTION	BATCH	Mfg. date	Exp. date	Manufacturer
Gastro-resistant Sodium valproate BP 500mg tablet	4S09201	02/2022	01/2025	4Care Lifescience Pvt Ltd/India
Gastro-resistant sodium valproate BP 300 mg tablet	4S08201	02/2022	01/2025	4Care Lifescience Pvt Ltd/India

607

Action to be taken

- Rwanda Food and Drug Authority instructs all importers, central medical stores, wholesalers, all RMS branches, retailers, Public and Private Health Facilities to stop the distribution and dispensing of the above incriminated medicines, and return them to the suppliers for suitable management.
- The importers and suppliers of incriminated batches of Gastro-resistant Sodium valproate are requested to report to Rwanda FDA within 15 days from the date of the recall the quantities imported, distributed, quantities returned, and final stock on hand.

Note: For more information or to report any suspected poor quality products please call toll free number 0789193529 or send an email to: pv_sm@rwandafda.gov.rw

You will find pictures for these medicines with quality issue as attachment.

Sincerely,



Dr. Emile BIENVENU
Director General

Photo of recalled medicines

