



## Rwanda Food and Drugs Authority

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QMS N°: FDISM/PVSM/FMT/034

Revision No: 0

Effective Date: 31/03/2023

### RECALL NOTIFICATION

Ref. No.: FDISM/PVSM/...../FDA/20<sup>23</sup>

**Central medical stores (All)**  
**RMS branches (All)**  
**Pharmaceutical Wholesalers (All)**  
**Importers (All)**  
**Retail Pharmacies (All)**  
**Public and private Health facilities (All)**  
**Health professionals (All)**

**Title:** Recall of all batches of Gastro-Resistant sodium valproate tablets BP 300mg and Gastro-Resistant sodium valproate tablets BP 500mg manufactured by 4care Lifescience Pvt Ltd/India

**Type of the recall:** Statutory

**Class of the recall:** Class II

**Recall level:** Retail / Facility level

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 regulation No.CBD/TRG/019 Rev\_1 governing the Recall, Treatment and Disposal of Unfit regulated products in its article 6

Reference is also made to the letter ref. No: FDISM/PVSM/417/FDA/2023 of 27/01/2023 recalling some batches of Gastro-resistant sodium valproate BP 500mg and 300 mg tablets manufactured by 4 Care Lifescience Pvt Ltd / India;

Further reference is made to the deep investigation and laboratory quality control analysis performed by Rwanda FDA on additional reported batches of Gastro-resistant sodium valproate BP 500mg and 300 mg tablets manufactured by 4 Care Lifescience Pvt Ltd / India which confirmed that the medicines do not meet quality standards and the issue is generalized to all batches countrywide;

It is with this background that Rwanda FDA recalls from the Rwandan market all batches of Gastro-resistant sodium valproate BP 500mg and 300 mg tablets manufactured by 4 Care Lifescience Pvt Ltd / India and stops importation of the below products:

Description	Batch	Mfg. date	exp. date	Manufacturer	Quality issue
Gastro-Resistant sodium valproate tablets BP 300mg	All	All	All	4Care Lifescience Pvt ltd/India	The tablets become semi-solid and cracked
Gastro-Resistant sodium valproate tablets BP 500mg	All	All	All	4Care Lifescience Pvt Ltd/India	The tablets become semi-solid and cracked

### **Action to be taken**

- Rwanda Food and Drugs Authority instructs all importers, central medical stores, wholesalers, RMS branches, retailers, public and private health facilities to stop the distribution of all batches of Gastro-resistant sodium valproate BP 500mg and 300 mg tablets manufactured by 4 Care Lifescience Pvt Ltd / India and return the products to their suppliers for proper management.
- The importers and suppliers of Gastro-resistant sodium valproate BP 500mg and 300 mg tablets manufactured by 4 Care Lifescience Pvt Ltd / India are requested to report to Rwanda FDA within 10 days from the date of publication of this recall, the quantities imported, quantities distributed, quantities returned and final stock on hands.
- Rwanda FDA will communicate officially when importation of Gastro-Resistant sodium valproate tablets BP 300mg and Gastro-Resistant sodium valproate tablets BP 500mg manufactured by 4care Lifescience Pvt Ltd/India will be permitted after the registration of the mentioned products

**Note:** For more information or to report any suspected poor quality products please call toll free number 9707 or 0789193529 or send email to: [pv\\_sm@rwandafda.gov.rw](mailto:pv_sm@rwandafda.gov.rw).

Sincerely,

*for*  
*[Signature]*

**Dr. Emile BIENVENU**  
**Director General**





Picture of recalled products:

