



Kigali on 27/01/2023

Ref. N°: FDISM/PVSM/418/FDA/2023

- Abinjiza imiti mu Rwanda (Bose)
- Abaranguza imiti (Bose)
- Amavuriro ya Leta n'ayigenga(Bose)
- Abadandaza imiti (Bose)
- Abaganga n'abahanga mu by'imiti (Bose)
- Abakoresha imiti (Bose)

Impamvu: Guhagarika ikwirakwizwa n'ikoreshwa rya nimeru zimwe z'imiti ya Gastro-resistant Sodium valproate 500mg na 300 mg y'ibinini ikorwa n'uruganda rwitwa 4Care Lifescience Pvt Ltd /mu Buhinde.

Dushingiye ku itegeko N° 003/2018 ryo kuwa 09/02/2018 rishyiraho ikigo cy'Igihugu gishinzwe kugenzura ibiribwa n'imiti (Rwanda FDA) cyane cyane mu ngingo yaryo ya 8, igika cya 2 n'icya 13;

Hashingiwe kandi kuri raporo zakiriwe na Rwanda FDA kuri nimeru zitandukanye z'umuti wa Gastro-resistant Sodium valproate 500mg na 300 mg w'ibinini itujuje ubuziranenge;

Hashingiwe na none ku busesenguzi bwimbitse bwakozwe na Rwanda FDA n'ibipimo by'ubuziranenge byapimwe na laboratwari byagaragaje ko nimeru zimwe z'umuti ya Gastro-resistant Sodium valproate 500mg na 300 mg ikorwa n'uruganda 4Care Lifescience Pvt Ltd itujuje ubuziranenge;

Kubw'ibyo, Rwanda FDA ihagaritse ikwirakwizwa n'ikoreshwa rya nimeru z'imiti igaragara mu mbonerahanwe ikurikira:

IZINA RY'UMUTI	NIMERO Y'UMUTI	IGIHE WAKOREWE	IGIHE UZARANGIRIRA	URUGANDA RWAWUKOZE
Gastro-resistant Sodium valproate 500mg w'ibinini	4S09201	28/02/2022	31/01/2022	4Care Lifescience Pvt Ltd /India
Gastro-resistant sodium valproate BP 300 mg w'ibinini	4S08201	02/2022	01/2025	4Care Lifescience Pvt Ltd/India

Can

Rwanda FDA irasaba:

- Abinjiza imiti mu gihugu bose, farumasi ziranguza, zidandaza, amashami yose ya RMS Ltd, amavuriro ya leta n'ayigenga guhagarika gutanga no kugurisha nimero z'umuti wavuzwe haruguru bakawusubiza aho bawuranguriye
- Abinjije iyi miti mu gihugu barasabwa gutanga raporo kuri Rwanda FDA igizwe n'imibare y'ingano y'uwo baranguye, uwo bagurishije, uwagaruwe ndetse n'ingano yose bazaba bafite mu gihe cy'iminsi cumi n'itanu uhereye ku itariki y'iri hagarikwa.

Icyitonderwa: Ku bindi bisobanuro ndetse no gutanga amakuru ajyanye n'ubuziranenge bw'imiti bukemangwa mwahamagara kuri numero igendanwa 0789 193 529 cyangwa mukatwoherereza email kuri pv_sm@rwandafda.gov.rw

Murabona amafoto y'imiti ya Gastro-resistant Sodium valproate 500mg na 300 mg y'ibinini kuri paji ikurikira.

Murakoze,



Dr. Emile BIENVENU
Umuyobozi Mukuru

Photo of recalled medicines

**GASTRO-RESISTANT
SODIUM VALPROATE TABLETS BP
500 mg**

10 x 10 Tablets

**GASTRO-RESISTANT
SODIUM VALPROATE TABLETS BP
300 mg**

10 x 10 Tablets