RWANDA FDA
Rwanda Food and Drugs Authority

Kigali on 18/01/2023
Ref. N°: FDISM/PVSM/251/FDA/20.23

Abinjiza imiti mu Rwanda (Bose)
Abaranguza imiti (Bose)
Abadandaza imiti (Bose)
Abaganga (Bose)
Abayobozi b'amavuriro ya Leta n'ayigenga (Bose)
Abakoresha imiti (Bose)

Impamvu: Guhagarika ikwirakwizwa n'ikoreshwa rya nimero z'imiti ya Hyoscine Butylbromide Tablets BP 10mg na Aminophylline Tablets USP 100mg

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 na none ku busesenguzi bwimbitse bwakozwe na Rwanda FDA n'ibipimo by'ubuziranenge byapimwe na laboratwari byagaragaje ko nimero z'imiti ya Hyoscine Butylbromide Tablets BP 10mg ifite nimero 22HB01 na Aminophylline Tablets USP 100mg ifite nimero 22AP01 itujuje ubuziranenge;

Kubw'ibyo Rwanda FDA ihagaritse ikwirakwizwa n'ikoreshwa ry'izo nimero z'imiti mu Rwanda nkuko iyo miti igaragara mu mbonerahamwe ikurikira:

IZINA RY'UMUTI	NIMERO Y'UMUTI	IGIHE WAKOREWE	IGIHE UZARANGIRIRA	URUGANDA RWAWUKOZE	IKIBAZO IMITI IFITE
Hyoscine Butylbromide Tablets BP 10mg	22HB01	04/2022	03/2025	MORKASH PHARMACEUTICALS PVT LTD/India	Kuvunguka kw'ibinini
Aminophylline Tablets USP 100mg	22AP01	04/2022	03/2025	MORKASH PHARMACEUTICALS PVT LTD/India	Ibinini byahinduye ibara

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Rwanda FDA irasaba:

- Abinjiza imiti mu gihugu bose, Farumasi ziranguza, furumasi zidandaza, amashami yose ya RMS Ltd, amavuriro ya leta n'ayigenga guhagarika gutanga no kugurisha nimero z'imiti yavuzwe haruguru bakayisubiza aho bayiranguriye
- 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 icumi (10) uhereye ku itariki iri tangazo ryasohoreweho.

Icyitonderwa: Ku bindi bisobanuro ndetse no gutanga amakuru ajyanye n'ubuziranenge bw'imiti bukemangwa mwahamagara kuri numero igendanwa **0789 193 529** cyangwa numero itishyuzwa **9707** cyangwa mukatwohereza email kuri **pv_sm@rwandafda.gov.rw**

Murakoze

E. [signature] 18/01/2023

Dr. Emile BIENVENU
Umuyobozi Mukuru

RWANDA FOOD AND DRUGS AUTHORITY · RWANDA FDA
REPUBULIKA Y'U RWANDA

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