Rwanda Food and Drugs Authority
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QMS Nº: FDISM/PVSM/FMT/034
Revision No: 0
Effective Date: 31/03/2023

GUHAGARIKA UMUTI

Kigali kuwa 07 / 10 / 2023
Ref. No.: FDISM/PVSM/4190/FDA/2023

Abafite ububiko bw'imiti (Bose)
Amashami ya RMS Ltd. (Yose)
Farumasi ziranguza imiti (Zose)
Abinjiza imiti mu Rwanda (Bose)
Farumasi zidandaza/zicuruza imiti (Zose)
Amavuriro ya Leta n'ayigenga (Yose)
Abaganga n'Abahanga mu by'imiti (Bose)

Impamvu: Guhagarika gukwirakwiza, gukoresha no kwinjiza mu gihugu umuti witwa Misoprostol 200 mcg w'ibinini ukorwa n'uruganda rwitwa Angel Biogenic Private Ltd rwo mu Buhinde.

Ubwoko bw'ihagarikwa: Ihagarikwa ritegetswe n'ubuyobozi

Icyiciro cy'ihagarikwa: Icyiciro cya I

Urwego rw'ihagarikwa: Kugeza ku mavuriro no kubadandaza imiti

Hashingiwe ku itegeko Nº 003/2018 ryo kuwa 09/02/2018 rishyiraho Ikigo cy'Igihugu gishinzwe Kugenzura Ibiribwa n'Imiti mu Rwanda (Rwanda FDA) cyane cyane mu ngingo yaryo ya 8, igika cya 2 n'icya 13; ndetse no ku mabwiriza No.: CBD/TRG/019 agenga ihagarikwa ry'imiti itujuje ubuziranenge mu gika cyayo cya 6;

Hashingiwe kandi ku itangazo nimero PVSM/FDIC/643/FDA/2023 ryo kuwa 15 Gashyantare 2023 ryahagarikaga by'agateganyo nimero zimwe na zimwe z'umuti wa Misoprostol 200 mcg w'ibinini;

Hashingiwe ku busesenguzi bwimbitse bwakozwe na Rwanda FDA. Hashingiwe nanone ku bipimo bya laboratwari kuri nimero zitandukanye z'umuti wavuzwe haruguru aho byagaragaje ko umuti wa Misoprostol 200 mcg w'ibinini ukorwa n'uruganda rwitwa Angel Biogenic Private Ltd rwo mu Buhinde utujuje ibipimo by'ubuziranenge kandi icyo kibazo kikaba kitari umwihariko kuri nimero runaka;

Kubw'ibyo, Rwanda FDA

- ihagaritse ikwirakwizwa n'ikoreshwa rya nimero zose z'umuti witwa Misoprostol 200 mcg w'ibinini ukorwa n'uruganda rwitwa Angel Biogenic Private Ltd rwo mu Buhinde.
- ihagaritse kwinjiza mu Gihugu nimero zose z'uyu muti.

<u>Impamvu y'ihagarikwa</u>

Ibi binini bifite ingano nke cyane y'umuti nyawo ugenwe muri buri kinini, ibyo bigatuma ugaragaza ubushobozi buke bwo kuvura.

<u>Ibigomba gukorwa</u>

- Rwanda FDA irasaba abinjiza imiti mu gihugu bose, amashami yose ya RMS Ltd, farumasi ziranguza n'izidandaza imiti, amavuriro ya leta n'ayigenga guhagarika gutanga no gukoresha nimero zose z'umuti wa Misoprostol 200 mcg w'ibinini ukorwa n'uruganda rwitwa Angel Biogenic Private Ltd rwo mu Buhinde ugasubizwa aho waranguwe;

- Abinjije uwo muti mu Rwanda barasabwa gushyikiriza raporo Rwanda FDA igizwe n'imibare y'ingano y'uwo muti baranguye, iyo bagurishije, iyagaruwe ndetse n'ingano yose bazaba bafite mu gihe cy'iminsi itatu (3) uhereye ku itariki y'iri hagarikwa.

<u>Icyitonderwa:</u> Ku bindi bisobanuro ndetse no gutanga amakuru ajyanye n'ubuziranenge bw'imiti bukemangwa mwahamagara kuri 9707 cyangwa 0788771663; mushobora no kutwohererereza email kuri pv_sm@rwandafda.gov.rw.

Murakoze,

Digitally signed by Rwanda FDA (Director General)
Date: 2023.10.07 15:36:49 +02'00'

Dr. Emile BIENVENU
Umuyobozi Mukuru

Amafoto y'umuti wahagaritswe: