Kigali on; 14/04/2021

Ref Nº: DIS/ 1283 /FDA/2021



Abinjiza imiti mu gihugu (Bose)

Abaranguza imiti (Bose)

Abadandaza imiti (Bose)

Abaganga (bose)

Abakoresha imiti (Bose)

Impamvu: Guhagarika ikwirakwizwa n'ikoreshwa rya nimero y'umuti witwa Erythromycin Estolate Oral Suspension USP 125mg/5ml (AGOMYCIN)

Dushingiye ku itegeko N° 003/2018 of 09/02/2018 rishyiraho ikigo cy'igihugu gishinzwe kugenzura ibiribwa n'imiti (Rwanda FDA) cyane cyane mu ngingo yaryo ya 8, igikacya 2 nicya 13.

Hashingiwe kandi kuri raporo ya Laboratwari ku bipimo by'ubuziranenge byakozwe mu rwego rwo gukurikirana imikoreshereze n'ubuziranenge bw'imiti yageze ku isoko. ikigo cy'igihugu gishinzwe kugenzura ibiribwa n'imiti (Rwanda FDA) kiramenyesha ko numero y'umuti uri mu imbonerahamwe ikurikira wagaragaweho ko ibipimo by'umuti wa Erythromycin Estolate urimo kurugero rwo hasi,kubera iyo mpamvu Rwanda FDA ihagaritse ikwirakwizwa n'ikoreshwa rya nimero y'uwo muti.

IZINA RY'UMUTI	NUMERO	IGIHE	IGIHE	URUGANDA
DYA	TA	WAKOREWE	UZARANGIRIRA	RWAWUKOZE
Erythromyc in Estolate	L96013	Nov.2019	Oct.2022	AGOG Pharma
Oral Suspension USP				Limited, India
125mg/5ml/AGOMYCIN	a Foo	d and I	Drugs Au	chority
Suspension				

Icyo dusaba gukora

- Rwanda FDA irasaba za farumasi ziranguza, zidandaza, amavuriro ya leta n'ayigenga guhagarika gutanga no kugurisha nimero y'uwo muti wavuzwe haruguru bakawusubiza aho bawuranguriye
- Abinjije uyu muti mu gihugu barasabwa gutanga raporo kuri Rwanda FDA igizwe n'imibare y'ingano y'uwo baranguye, iyagurishijwe, iyagaruwe ndetse n'ingano yose bazaba bafite

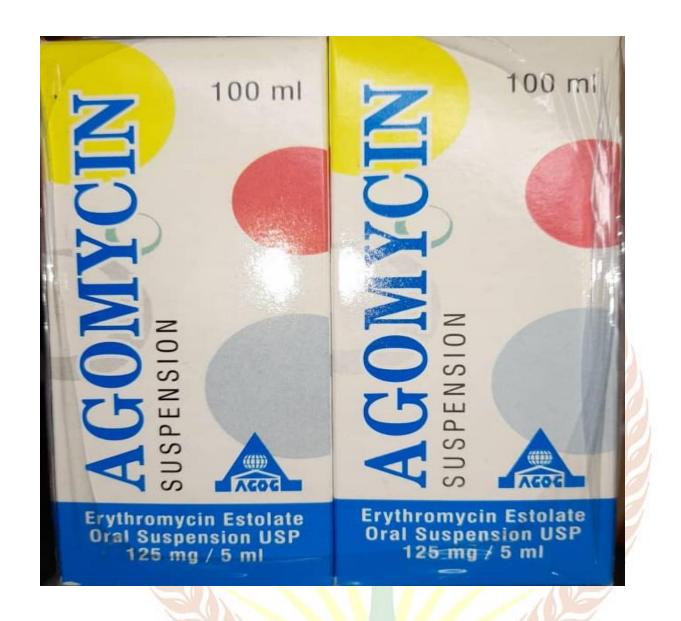
<u>Icyitonderwa:</u> Abashaka gusaba ibisobanuro ndetse no gutanga amakuru ajyanye n'ubuziranenge bw'imiti bukemangwa bahmagara kuri **0789193529** cyangwa bakatwoherereza email kuri <u>pv_sm@rwandafda.gov.rw</u>

Murabona amafoto y'ubwoko bw'uwomuti kuri paji ikurikira

Murakoze

Dr. Charles KARANGWA Umuyobozi mukuru w'agateganyo





RWANDA FDA Rwanda Food and Drugs Authority