



RWANDA FDA
Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

Kigali on; *25/05/2021*
 Ref N°: DIS/ *1858* /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 75363 y'umuti
 Azithromycin dry suspension 200mg/5ml (ZEROCIN®).

Dushingiye ku itegeko N° 003/2018 of 09/02/2018 rishyiraho ikigo cy'ighugu gishinzwe kugenzura ibiribwa n'imti (Rwanda FDA) cyane cyane mu ngingo yaryo ya 8, igika cya 2 n'icya 13.

Hashingiwe kandi kuri raporo yagejejwe ku kigo cy'ighugu gishinzwe kugenzura ibiribwa n'imti (Rwanda FDA) no kubusesenguzi bwimbitse ndetse n'ibipimo bya Laboratoire bwakozwe n'ikigo cy'ighugu gishinzwe kugenzura ibiribwa n'imti (Rwanda FDA) kuri nimero y'umuti Azithromycin dry suspension 200mg/5ml (ZEROCIN®) byagaragaje ko umuti wavuzwe utujuje ubuziranenge ukaba ifu yawo yarafatanye bityo bikaba bituma utabasha gushonga mumazi mugihe cyo kuwutegura.

Kubw'ibyo Rwanda FDA ihagaritse ikwirakwizwa n'ikoreshwa mu Rwanda rya nimero ikurikira y'uwo muti:

| No | IZINA RY'UMUTI | NIMERO | ITARIKI UZARANGIRIRAH O | URUGANDA |
|----|--|-----------|-------------------------|--------------------------------|
| 1 | Azithromycin dry suspension 200mg/5ml (ZEROCIN®) | No: 75363 | 08/2021 | Laboratory & Allied Ltd, Kenya |

Icyo dusaba gukora

- Rwanda FDA irasaba za farumasi ziranguza, izidandaza, amavuriro ya leta n'ayigenga guhagarika ikwirakwiza n'ikoreswa rya nimo 75363 y'umuti Azithromycin dry suspension 200mg/5ml (ZEROCIN®), bakayisubiza aho bayiranguriye.
- Abinjije uyu muti mu gihugu barasabwa gutanga raporo kuri Rwanda FDA igizwe n'imibare y'ingano y'uwo baranguye, iyagurishijwe, iyagaruve ndetse n'ingano yose bazaba bafite mugihe kitarengeje iminsi icumi (10)
- Birabujije kwinjiza mu gihugu umuti wa Azithromycin dry suspension 200mg/5ml (ZEROCIN®) ukorwa n'uruganda rwa Laboratory & Allied Ltd, Kenya kugeza igihe harangiye igikorwa cyo kuwandika cyijyana n'igenzura rya GMP kuruganda ruwukora. Rwanda FDA izamenesha igahe bizaba byemewe kuwinjiza mugihugu

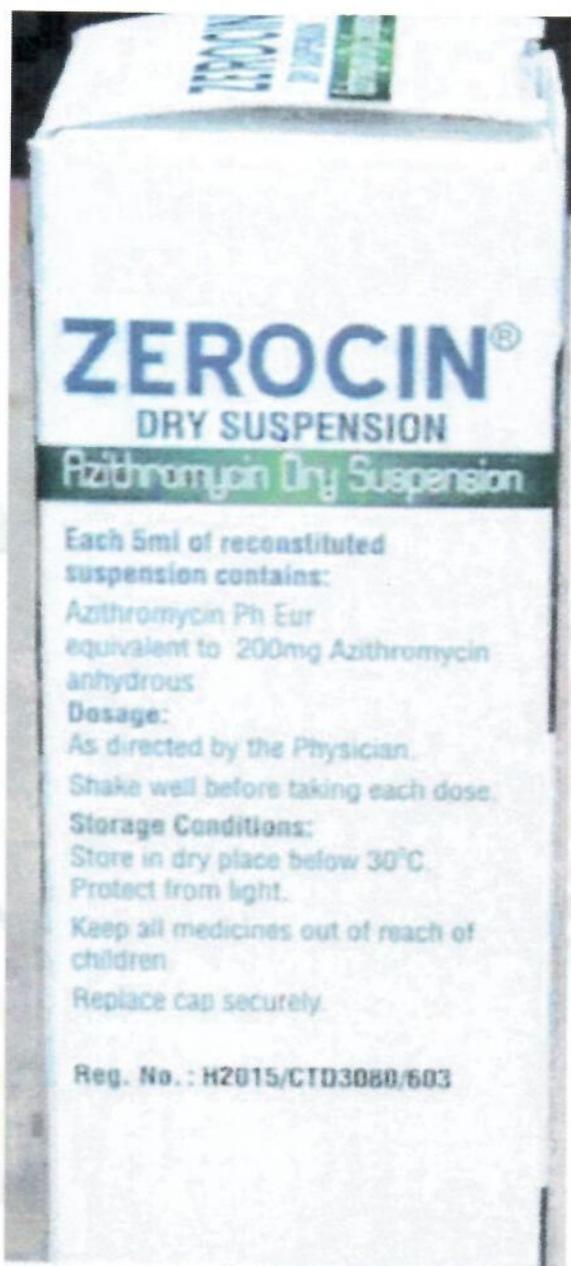
Icyitonderwa: Abashaka gusaba ibisobanuro ndetse no gutanga amakuru ajyanye n'ubuziranenge bw'imihi bukemangwa bahamagara kuri **0789193529** cyangwa **9707**, **mushobora no kutwoherereza** email kuri pv_sm@rwandafda.gov.rw

Ubuyobozi bwa Rwanda FDA buha agaciro amakuru yose aturuka ku bafatanyabikorwa kugira ngo imiti yizewe igere kubatuye u Rwanda.

Murabona amafoto y'uwo muti kumugereka w'iri tangazo.

Murakoze

Dr. Charles KARANGWA
Umuyobozi mukuru w'agateganyo



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