



RWANDA FDA

Rwanda Food and Drugs Authority

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Kigali on; 14/04/2021

RefN°: DIS/1257/FDA/2021

Public and private Health facilities (All)

Central medical stores (All)

Pharmaceutical Wholesalers (All)

Importers (All)

Retail Pharmacies (All)

Title: Recall for a batch of Telmisartan USP 40mg tablet/Telmi Tab40

Reference is made to the **Law N° 003/2018 of 09/02/2018** establishing Rwanda Food and Drugs Authority especially in its article 8 paragraph 2 and 13.

Reference is also made to the spontaneous reports received by the Authority from retail Pharmacies on Telmisartan USP 40mg tablet/Telmi Tab 40 with Batch number **FF9016** where the medicines were reported to have an issue of tablet softness associated with tablet cracking.

Further reference is made to deep investigations conducted by Rwanda FDA, where samples for the mentioned medicines failed the laboratory quality control test. It is in that regard that Rwanda FDA Recalls from the market Telmisartan tablets with the following description:

DESCRIPTION	BATCH	Mfg date	Exp date	Manufacturer
Telmisartan USP 40mg tablet/Telmi Tab40	FF9016	06/2019	05/2022	FREDUN Pharmaceuticals Ltd.14,15,16 Zorbian Industrial Complex,Vevoor,Palghar(E)- 401 404,India

Action to be taken

- Rwanda Food and Drug Authority instructs all importers, central medical stores, wholesalers, District Pharmacies, retailers, Public and Private Health Facilities to stop the distribution of the above incriminated batch of Telmisartan USP 40mg tablet/Telmi Tab40 and return them to the suppliers for suitable management.
- The importers and Suppliers of the incriminated batch of Telmisartan USP 40mg tablet/Telmi Tab40 are requested to report to Rwanda FDA within 10 working days, the quantities imported, quantities distributed, quantities returned and final stock on hand

Note: For more information or to report any suspected poor quality products please call **0789193529** or send email to: pv_sm@rwandafda.gov.rw

You will find pictures of the recalled medicine as attachment.

Sincerely,

Dr. Charles KARANGWA
Ag. Director General

The logo of the Rwanda Food and Drug Authority (FDA) is centered in the background. It features a stylized green and blue caduceus (a staff with two snakes) set against a yellow sunburst. The entire emblem is framed by a circular wreath of brown and white leaves.

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TELMITAB 40

Telmisartan Tablets USP 40 mg

3x10 Tablets
3x10 Comprimés
3x10 Comprimidos



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