

ML-COTRI SUSPENSION
(Co-trimoxazole oral suspension BP 240 mg)



Rwanda Food and Drugs Authority

Ref. N°: DFAR/HMDAR/3551/FDA/2023

PRODUCT:

ML-COTRI SUSPENSION
(Co-trimoxazole oral suspension BP 240 mg)

Submitted by:

MILAN LABORATORIES (INDIA) PVT.LTD.

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ML-COTRI SUSPENSION

(Co-trimoxazole oral suspension BP 240 mg)



Query –

Reference is made to your product recently registered under the name **ML-COTRI SUSPENSION** manufactured by **Milan Laboratories (India)** with Registration number **Rwanda FDA-HMP-MA-0468**

You are requested to submit the product information: Patient Information Leaflet (PIL). Please ensure compliance with our regulatory requirements and provide the product information in line with Guidance on format and content of SmPC, PIL, and Labels available on Rwanda FDA website. Please ensure to follow the format and include the information as:

- a. What ML-Cotri Suspension is and what it is used for,
- b. Before you <take><use> ML-Cotri Suspension
- c. How to<take><use> ML-Cotri Suspension
- d. Possible side effects
- e. How to store ML-Cotri Suspension
- f. Further information

The SmPC and PIL will be published on Rwanda FDA website and the information should be in line with the set requirements in the above-mentioned guidelines, and the content should be clear for patient' easy guidance and understanding.

Reply – Please refer to attached the product information: Patient Information Leaflet (PIL).