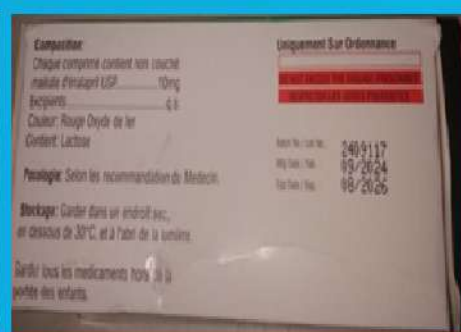




Public Alert Notice on Unauthorized Enalapril Maleate (Dawapril 10) 10mg Tablet

Medical Product Alert 12/2025



Alert Summary

The Ethiopian Food and Drug Authority is mandated by Article 38 of the Food and Medicine Administration Proclamation No. 1112/2019 to conduct periodic monitoring of the safety, quality, and efficacy of medicines through surveillance activities.

The Authority received a product quality defect complaint concerning Enalapril Maleate 10 mg tablet (Dawapril 10). In response, the Authority assessed the complaint, conducted an investigation, and carried out market surveillance to verify the presence of the product in the market. The investigation revealed that the product is unregistered and not authorized for marketing by the Ethiopian Food and Drug Authority.

Brief Description of the Product

- Generic Name: Enalapril Maleate 10 mg Tablet
- Brand Name: Dawapril 10
- Batch Number: 2409117
- Manufacturing Date: September 2024
- Expiry Date: August 2026
- Manufacturer: Dawa Limited, Nairobi, Kenya

Risk Summary

This unauthorized product may be unsafe and poses significant health risks, particularly for patients who rely on Enalapril Maleate for the treatment of heart failure, chronic hypertension, and asymptomatic left ventricular dysfunction.

Because the product is not evaluated, tested, or authorized by a regulatory authority, its safety, quality, and efficacy cannot be guaranteed. The use of such a product may result in:

- Lack of therapeutic effect, leading to poor disease control or progression
- Adverse drug reactions (ADRs) due to unknown or substandard ingredients
- Potential drug interactions stemming from unverified active or inactive components

Patients using this product are at risk of serious clinical consequences, and healthcare providers are advised to exercise caution, report any suspected adverse events, and avoid dispensing or using unregistered products.

How to identify the unauthorized product

The unauthorized product was identified by checking the registration status of the product at the EFDA database and also by communicating with the manufacturer stated in its secondary packaging.

Target Audiences

• Advice to Healthcare professionals

The Authority intends to alert healthcare professionals about the urgent need to detect, report, and remove the circulation and administration of the unauthorized product to prevent potential harm to patients.

Healthcare providers are urged to verify the registration status of medicines before prescribing, dispensing, or administering them and to immediately report any suspected unauthorized products to the Ethiopian Food and Drug Authority (EFDA). In addition, patients are strongly advised to refrain from using the unregistered and unauthorized Enalapril Maleate 10 mg tablets (Dawapril 10), as their safety, quality, and efficacy have not been verified by the Authority.

• Advice to Regional Regulatory Bodies

The Authority also intends to alert regional regulatory bodies to intensify monitoring of the circulation and use of this unauthorized product within their respective jurisdictions. Collaborative efforts at all levels are essential to ensure that such unregistered medicines are identified, removed from the supply chain, and do not reach patients.

• Advice to Public

If you are in possession of this unauthorized product, do not use it under any circumstances.

If you or anyone you know has used this product or has experienced any adverse reaction or health issue following its use, you are strongly advised to seek immediate medical attention from a qualified healthcare professional.

Report Adverse Events

The EFDA encourage members of the public and health care professionals to report all suspicious, substandard and falsified medicinal products to the Ethiopia Food and Drug Authority through, ADE reporting form, Med safety mobile apps available at play store for androids and app store for iPhone, E-reporting available on EFDA website (www.efda.gov.et), through email pharmacovigilance@efda.gov.et and Toll-free number 8482.