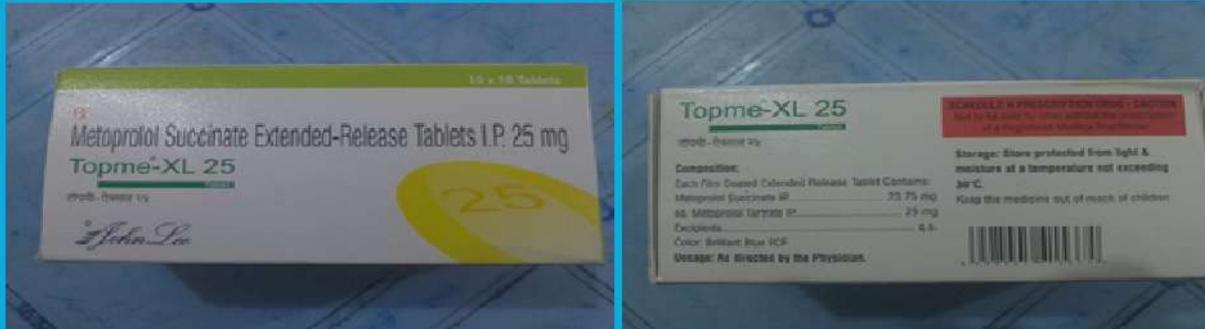




Public Alert Notice on unauthorized Metoprolol Succinate (Topme-XL25) extended-release 25 mg tablet,

Medical Product Alert 11/2025



Alert Summary

The Ethiopia Food and Drug Authority is mandated by article 38 Food and Medicine Administration Proclamation No. 1112/2019 to performe periodic monitoring of the safety, quality, and efficacy of medicine through survilance.

The Ethiopian Food and Drug Authority (EFDA) has received a product quality defect complaint regarding Metoprolol Succinate Extended-Release 25 mg Tablets, branded as Topme-XL 25. In response, the Authority assessed the complaint, carried out an investigation, and conducted market surveillance to verify the presence of the product in the local market.

The investigation revealed that the product is unregistered and unauthorized for marketing by the Ethiopian Food and Drug Authority.

Brief Description of the Product

- Generic Name: Metoprolol Succinate (Extended-Release)
- Brand Name: Topme-XL 25
- Strength: 25 mg Tablet
- Batch Number: 40921
- Manufacturing Date: December 2024
- Expiry Date: November 2026
- Manufacturer: UNIZA LIFE CARE PVT. LTD, India

Risk Summary

This unauthorized product may be unsafe and poses significant health risks, particularly for patients who are prescribed Metoprolol to manage serious cardiovascular conditions. These include:

- Lowering high blood pressure (hypertension)
- Preventing chest pain (angina) in patients with heart disease
- Reducing the risk of heart attack in individuals with a recent history of myocardial infarction
- Lowering the risk of hospitalization and death in patients with heart failure

The unregistered and unauthorized Metoprolol Succinate (Topme-XL 25) may not be efficacious in treating these conditions and could lead to treatment failure. Furthermore, its use may result in adverse drug reactions or dangerous drug interactions, as its active and inactive ingredients have not been evaluated, tested, or approved by the Ethiopian Food and Drug Authority.

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 communicating with the manufacturer stated in its secondary packaging.

Target Audiences

- **Advice to Healthcare Professionals**

The authority intends to alert healthcare professionals about the need to detect and remove unauthorized medicinal products from circulation and use in order to prevent 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). Patients are also advised to refrain from using unregistered and unauthorized Metoprolol tablets.

- **Advice to Regional Regulatory Bodies**

The authority also intends to alert regional regulatory authorities to monitor the circulation and use of the unauthorized product. 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 have this unauthorized product, please do not use it. If you or anyone you know has used this product or experienced any adverse reaction or event after its use, you are 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.