

Public Alert Notice on Unauthorized Metoprolol Succinate 50 (Metrate-XL50) mg Tablet, Medical Product Alert 07/2025

Alert Summary

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

The Authority has received a product quality defect report complaint regarding Metoprolol Succinate 50 mg tablets (Metrate-XL 50). In response, the Authority conducted a compliance assessment, initiated an investigation, and carried out market surveillance to verify the circulation of this product. The investigation confirmed that the product is unauthorized for marketing as a medication by the Authority.

Brief Description of the Product

- Product Name: Metrate-XL 50 mg (Metoprolol Succinate 50 mg Extended-Release Tablet)
- Batch Number: LGN08/014/08
- Stated Manufacturer: Logos Pharma
- Manufacturing Location: Village Maissa Tiba, Tehsil Nalagarha

Risk Summary

These Unauthorized products are unsafe and may pose significant health risks, particularly for patients with symptoms of various cardiovascular conditions, such as hypertension, angina, heart failure, and arrhythmias individuals.

The Unauthorized Metrate-XL50mg is not efficacious and should not be used to treatment symptoms of various cardiovascular conditions, such as hypertension, angina, heart failure, and arrhythmias.

How to Identify Unauthorized Products

By comparing authorized Metoprolol succinate 50mg tablet registered by the Ethiopian food and drug authority.

By comparing with the authorized Metoprolol Succinate 50 mg tablet registered by the Ethiopian Food and Drug Authority.

Target Audiences

Healthcare professionals

The Authority intends to alert healthcare providers about the importance of identifying and removing unauthorized medicinal products from circulation and clinical use to prevent patient harm. Additionally, patients are advised to avoid using the unauthorized Metrate-XL 50 mg tablet.

Advice to Regional Regulatory Bodies

The authority also intends to alert the regional regulatory bodies to monitor the circulation and use of unauthorized product.

Public Advice

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 provider 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.