Medical Product Alert Notice on Unauthorized Pantoprazole Sodium enteric coated Delayed-Release USP 40mg

Medical Product Alert

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 Ethiopian Food and Drug Authority (EFDA) has identified an unauthorized Pantoprazole Sodium enteric coated Delayed-Release USP 40mg tablet during post-marketing surveillance. The product lacks manufacturer information on both the primary and secondary packaging. Therefore, this product is unregistered and not authorized for marketing by the EFDA.

Brief Description of the Product

- Product Name: Pantoprazole Sodium enteric coated Delayed-Release USP 40mg
- Batch Number: AT486
- Manufacturing Date: Dec-23
- Expiry Date: Nov-26

Risk Summary

This unauthorized product may be unsafe and poses significant health risks, especially for patients who rely on Pantoprazole Sodium enteric coated Delayed-Release USP 40mg for the treatment of esophague and stomach heart burn.
Because the product is not evaluated, tested, or authorized by a regulatory authority, its safety, quality, and efficacy cannot be guaranteed.
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 verifying its registration status in the EFDA database. Additionally, no manufacturer information was found on either the primary or 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. In addition, patients are strongly advised to refrain from using the unregistered and Pantoprazole Sodium enteric coated Delayed-Release USP 40mg, 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 suspecious, 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 andToll-free number 8482.

EFDA
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