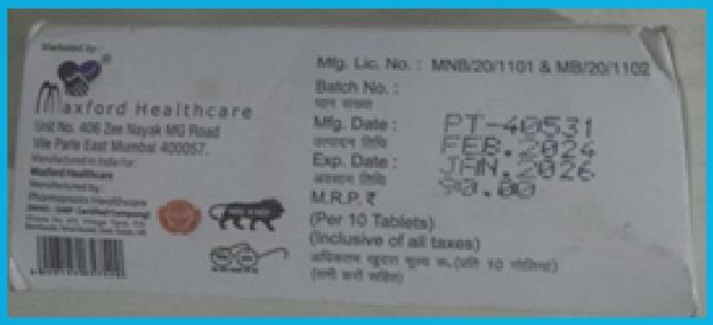
Public Alert Notice on unauthorized Tamsulosin hydrochloride (MR), Temros-0.4 tablet

Medical Product Alert 10/2025



Alert Summary

The Ethiopian Food and Drug Authority (EFDA) 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 regarding Tamsulosin Hydrochloride (MR) 0.4 mg Tablet. In response, the Authority assessed the complaint, conducted an investigation, and carried out market surveillance to verify the circulation of the product in the 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: Tamsulosin Hydrochloride (Modified Release)**
- **Brand Name: Temros 0.4 mg Tablet**
- **Batch Number: PT-40531**
- **Manufacturing Date: February 2024**
- **Expiry Date: January 2026**
- **Manufactured by: Pharma Roots Healthcare, India**
- **Manufactured for: Maxford Healthcare, India**

Risk Summary

This unauthorized product is considered unsafe and may pose significant health risks, particularly for patients experiencing symptoms of an enlarged prostate gland, which is also knwn as benign prostatic hyperplasia (BPH).

The unauthorized Tamsulosin Hydrochloride (MR) may lack efficacy and could potentially cause adverse drug reactions or harmful drug interactions, as its active and inactive ingredients have not been evaluated, tested, or authorized by the Ethiopian Food and Drug Authority. Use of such unregistered products may lead to treatment failure, worsening of symptoms, or serious health complications.

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 on its secondary packaging.

Target Audiences

- **Advice Healthcare Professionals**

The Authority intends to alert healthcare professionals about the urgent need to identify, report, and prevent the circulation and use of the unauthorized Tamsulosin Hydrochloride tablets in order to protect patients from potential harm.

Healthcare providers are strongly advised to verify the regulatory status of medicines before prescribing, dispensing, or administering them, and to take immediate action to remove any unauthorized products from their facilities. The Authority urges patients to refrain from using the unauthorized Tamsulosin Hydrochloride (Temros 0.4 mg) tablets, as their safety, quality, and efficacy have not been verified through proper regulatory evaluation.

- **Advice to Regional Regulatory Bodies**

The Authority also intends to notify regional regulatory bodies to closely monitor the circulation and use of the unauthorized product within their respective jurisdictions. Regional bodies are urged to intensify market surveillance efforts and take appropriate regulatory actions to prevent the distribution and use of unregistered medicines.

- **Advice to Public**

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

If you or anyone you know has used this product or 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 suspiscious, 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.

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