# Medical Product Alert on Falsified HEALMOXY Capsules 500mg

## Medical Product Alert No; 05/ 2025

The Ethiopia Food and Drug Authority is mandated by article 38 Food and Medicine Administration Proclamation 1112/2019 to performe periodic monitoring of the safety, quality and efficacy of medicine through survilance.

**Alert Summary**

The WHO Medical Product Alert(https://www.who.int/health-topics/substandard-and-falsified-medical-products) notification for four batch of HEALMOXY Capsules 500mg Stated manufacturer: MAXHEAL PHARMACEUTICALS (India) Limited the falsified products have been detected in Cameroon and the Central African Republic, and WHO annouce in March 2025.

The active pharmaceutical ingredient in genuine HEALMOXY capsules is amoxicillin: it is an antibiotic used to treat a variety of bacterial infections, including middle ear infections, pneumonia, skin infections, dental infections, and urinary tract infections.

Brief Description of the Product

HEALMOXY Capsules 500mg (Amoxicillin capsule BP 500 mg).

Batch No. 023011, H02605 and H0 26051

Expire Date: 18/07/2025,10/01/2027 ,02/2027 and 01/2026

Stated manufacturer: MAXHEAL PHARMACEUTICALS Limited, India

**Risk Summary**

These falsified products are unsafe and may pose significant health risks, particularly for severe infections or vulnerable individuals. The falsified HEALMOXY is not efficacious and should not be used to manage bacterial infections. Amoxicillin is an antibiotic that works by killing bacteria or preventing their growth. Without the active ingredient, these products would not be effective in treating the infection, which could lead to the infection worsening or spreading. It is crucial to detect and remove any falsified HEALMOXY from circulation to prevent harm to patients.

**How to identify these falsified products**

·By reviwing the WHO Medical product aler website https://www.who.int/health-topics/substandard-and-falsified-medical-products)

· The falsified product deliberately misrepresents their identity, composition, and source.

• Analysis of samples of the falsified HEALMOXY found the capsules did not contain the stated active ingredient, specifically amoxicillin.

• At least two of the falsified products display inconsistent formats for manufacturing and expiry dates. Dates on these falsified products are displayed as day/month/year in eight digits (e.g., 10/01/2027).

·In addition to, the information obtained from WHO Medical Product Alert by comparing the falsified product package's labeling with the authorized one. The authority identified the following differences:

-The falsified product's brand name is labeled in blue as "HEALMOXY Capsules 500mg including generic name in black color Amoxicillin capsule BP 500 mg" and has four color curved stripe marks on one side corner Whereas the Authorized product's brand name is labeled in purple color as "**HEALMOXY** the generic name written in black color as 'Amoxicillin BP 500 mg capsule'and the three-color curved stripe mark on both side corners of secondary package (yellow, purple, and green).

Based on this, the Ethiopian Food and Drug Authority investigated the market authorization status of the **HEALMOXY** (Amoxicillin BP 500 mg capsule') which is registered and approved for sale in Ethiopia.

**Target Audiences**

Advice to regional regulatory authorities,healthcare professionals, and Public

The authority also intends to alert the regional regulatory Authority so that it can monitor the circulation and usage of falsified product. To protect patients, the authority aims to inform health-careprofessionals on the necessity of detecting and eliminating Falsified medicinal products from circulation and administration/use. For the general public, if you have this falsified product, please do not use it. If you or anyone you know has used this product and has an adverse reaction/event, you should seek immediate medical advice from a qualified health care professional.

**Report Adverse Events**

The EFDA encourages members of the public and health care providers to report any suspicious, falsified, or substandard medical products to the Ethiopian 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.

# Picture of Falsified Product

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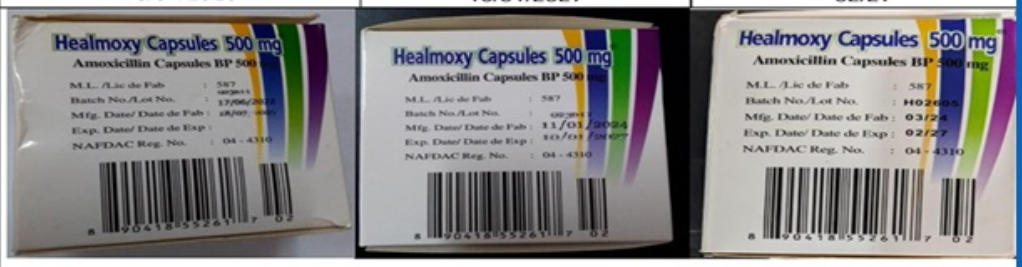
|---|---|---|---|
| **Product Name** | HEALMOXY Capsules 500mg | | |
| **Stated manufacturer** | MAXHEAL PHARMACEUTICALS (India) Limited | | |
| **Identified in** | Cameroon | | |
| **Batch** | 023011 | 023011 | H02605 |
| **Expiry date** | 18/07/2025 | 10/01/2027 | 02/27 |
| **Available Photographs** |     | | |

**WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products**
**Please visit:** https://www.who.int/health-topics/substandard-and-falsified-medical-products, or **e-mail:** rapidalert@who.int



World Health Organization

April 2025

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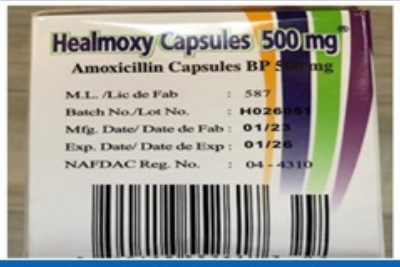
|---|---|
| **Product Name** | HEALMOXY Capsules 500mg |
| **Stated manufacturer** | MAXHEAL PHARMACEUTICALS (India) Limited |
| **Identified in** | Central African Republic |
| **Batch** | H026051 |
| **Expiry date** | 01/26 |
| **Available Photographs** |     |

# Picture of Registered Product