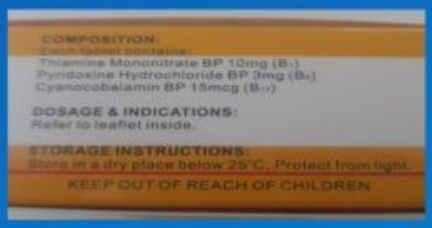
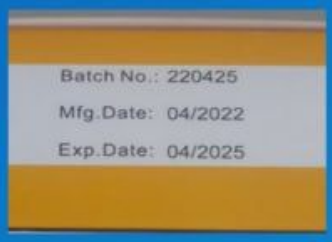
Public Alert Notice on Unauthorized and Substandard Nuration Sugar Coated Tablet

Medical Product Alert 03/2025





Alert Summary

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

The Authority has accepted a market compliant of quality defect Medicine from Drug Information Center at St. Peter's Specialized Hospital on **NURATION**. In light of this, the Authority assessed compliant, conducted an investigation, and did market surveillance to confirm the circulation of this product in the market. The investigation report indicated that the product is substandard and unauthorized to market as medication or food supplement

Brief Description of the Product

NURATION (10mg Thiamine monohydrate+3mg Pyridoxine Hydrochloride+15mcg Cyanocobalamin) sugar coated tablet; supplement. Batch No: 220425, Mfg. date: 04/2022 and Exp date: 04/ 2025, Zhejiang Medicine and Health Products Import and Export is the stated manufacturer.

Risk Summary

These Unauthorized products are unsafe and may pose significant health risks, particularly for sever vitamin B1, B6 and B12 deficient individuales

The Unauthorized NURATION is not efficacious and should not be used to treatment of nutritional vitamin B1, B6 and B12 deficiencies, peripheral neuritis and in conditions requiring increased intake such as alcoholism, hepatic disease, hyperthyroidism, infection, lactation, pregnancy and malabsorption syndromes.

How to identify these Falsified products

By comparing authorized SMPC of vitamin B1, B6 and B12 compostion with the unauthorized

	Name of authorized Product: Neurovit Film-Coated Tablet	**Name of unauthorized Product NURATION Film-Coated Tablet**
	Qualitative and quantitative compostion of active ingredient per tablet (mg	
1	Thiamine Mononitrate 97.00 mg	Thiamine Mononitrate 10 mg
2	Pyridoxine HCl 50.00 mg	Pyridoxine HCl 3 mg
3	Cyanocobalamin 100.00 mcg	Cyanocobalamin 15 mcg

Target Audiences

The authority intends to alert health care providers about the need to detect and remove circulation and administration/use of **unauthorizedand substandard** medicinal product to prevent harm to patients.

Advice to Regional regulatory authorities, Healthcare professionals, and Public

The authority also intends to alert the regional regulatory authority to monitor the circulation and use of unauthorized and substandard product. For the public if they have this unauthorized and substandard or out of specification product, please do not use it. If you, or any one you know have you used this product or suffered any adverse reaction/event after use you are advice to seek immediate medical advice from a qualified health care professional.

Report Adverse Events

The EFDA encourage members of the public and health care provider to report all sespecious, 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.