



All correspondence should be addressed to the Director General

LET\_LSE\_PMS\_0003/09/25

In reply, please quote

# ZAMBIA MEDICINES REGULATORY AUTHORITY

## PUBLIC NOTICE

Date: 4<sup>th</sup> September 2025

To: Public Health Facilities, Healthcare Professionals, General Public

### MEDICAL PRODUCT ALERT:

#### RECALL OF COMBIART (ARTEMETHER/LUMEFANTRINE) TABLETS 20/120MG BATCH NO. 5813323A MANUFACTURED BY UNIVERSAL CORPORATION LTD., KENYA

FOR IMMEDIATE RELEASE – The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia. The main mandate of ZAMRA is to ensure the quality, safety and efficacy of medicines and allied substances for human and animal health protection.

On this background, the Authority wishes to notify all healthcare professionals, public health facilities and members of the public that it has instructed Prime Pharmaceuticals Limited, Lusaka to urgently **RECALL** the above-stated product due to failure to meet its Appearance, Assay (for Artemether) and Weight Variation (for Artemether) specifications.

#### Product details:

S/N	Name of Product	Manufacturer	Batch Number	Mfg. Date	Expiry Date
1.	COMBIART (Artemether/Lumefantrine) Tablets 20/120mg	Universal Corporation Ltd., Kenya	5813323A	03/2024	02/2026

### RISK

COMBIART (ARTEMETHER/LUMEFANTRINE) TABLETS 20/120MG is indicated for the treatment of uncomplicated malaria in all age groups and is administered by the oral route. Reduced amounts of Artemether and the variation in the weight of the tablets may result in patients consuming a low amount than is required, and may lead to treatment failure.

The affected product was supplied to public health facilities through the Zambia Medicines and Medical Supplies Agency (ZAMMSA). If you are in possession of this batch of the product (i.e. **Batch No. 5813323A**), please return it to your healthcare provider who should replace it with another batch or brand. Public health facilities in possession of the

#### Head Office

Plot No: 2350/M  
Off Kenneth Kaunda International Airport Road.  
P.O. Box 31890, Lusaka, ZAMBIA  
Tel: +260 211 432 350 /432 351

E-mail: [pharmacy@zamra.co.zm](mailto:pharmacy@zamra.co.zm)

#### Report Adverse Reactions to:

Pharmacovigilance Unit, Lusaka  
Tel: +260 211 432 356

E-mail: [npvu@zamra.co.zm](mailto:npvu@zamra.co.zm)

Website: [www.zamra.co.zm](http://www.zamra.co.zm)

affected batch should quarantine the product and return it to ZAMMSA for collection and disposal by the importer.

If you suffer any adverse drug reaction having used this product, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone: +260 211 432 356/+260 //956 521 094 or email address at: [npvu@zamra.co.zm](mailto:npvu@zamra.co.zm) or [pharmacy@zamra.co.zm](mailto:pharmacy@zamra.co.zm).

Should you need further clarification, please do not hesitate to contact our Secretariat.



Makomani Siyanga (Mr)  
**DIRECTOR-GENERAL**