All correspondence should be addressed to the Director General

In reply please quote LET_LSE_PMS_0008/08/24

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ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 7th August, 2024

To: Distributors, Wholesalers, Retailers, Healthcare Professionals, General Public

MEDICAL PRODUCT ALERT NO. 3/2024: FALSIFIED (CONTAMINATED) OXYMORPHONE HYDROCHLORIDE 40MG TABLETS IDENTFIED IN THE WHO REGION FOR EUROPE

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 regulate, and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances for human and animal use for public health protection.

Based on the above, ZAMRA wishes to alert healthcare professionals, pharmaceutical outlets and members of the public of the circulation of one batch of falsified (contaminated) **Oxymorphone**. The falsified Oxymorphone Hydrochloride 40mg Tablets was detected in the unregulated (illegal) supply chain in Finland by the Finnish Medicines Agency (FIMEA). See products details in the annex below.

Oxymorphone Hydrochloride is a semi-synthetic opioid medicine used to treat moderate to severe pain. Laboratory analysis of the samples of the falsified product found that the tablets contained metonitazene instead.

Metonitazene is a psychoactive opioid drug, with no official recognised or authorised medicinal or therapeutic use. Small doses can result in serious adverse effects such as respiratory depression, severe sedation, addiction, and death when overdosed.

Risk

This falsified product has been intentionally made to mimic products authorised by the U.S. Food and Drug Administration and marketed by AUROLIFE PHARMA LL as Oxymorphone Hydrochloride. However, since this product contains undeclared metonitazene, it poses significant risk to end users due to the high likelihood of adverse events, even in small doses. Metonitazene has high potency and therefore carries a high risk of overdose and death. Use of this product may be life-threatening.

ZAMRA wishes to notify healthcare professionals and members of the public that, while this product is not registered in Zambia, the ZAMRA has intensified surveillance of the product on the Zambian market as it may be imported through illegal means.

In the unlikely event that you are in possession of this product, do not use it. If you suffer any adverse drug reaction/event having used this product, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia

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

Report Adverse Reactions to:
Pharmacovigilance Unit, Lusaka
Tel: +260 211 432 356
E-mail: npvu@zamra.co.zm
Website: www.zamra.co.zm

Medicines Regulatory Authority by phone: +260 211 432 356/+260 //956 521 094 or email address at: npvu@zamra.co.zm or pharmacy@zamra.co.zm.

Should the public need further clarification, please do not hesitate to contact the Secretariat.

Makomani Siyanga (Mr)
DIRECTOR-GENERAL

Annex: details of the falsified Oxymorphone Hydrochloride Tablets

How to identify this falsified product

To identify this falsified product, check for the following:

- The falsified version label does not have a barcode on the bottle;
- The falsified version is labelled 40mg. AUROLIFE PHARMA Oxymorphone Hydrochloride is only available as 5mg and 10mg doses;
- The falsified versions of the tablets lack embossed letters/numbers;
- The falsified product's label is missing the National Drug Code of the United States of America.

Annex: Products subject of WHO Medical Product Alert No. 3/2024

Product Name	Oxymorphone Hydrochloride 40mg
Stated manufacturer	Aurobindo Pharma Limited, Hyderabad-500 038, India
Batch	H20330826
Expiry date	08/2026
Identified in	Finland
Available photos