

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার  
ঔষধ প্রশাসন অধিদপ্তর  
ঔষধ ভবন, মহাখালী, ঢাকা  
[www.dgda.gov.bd](http://www.dgda.gov.bd)

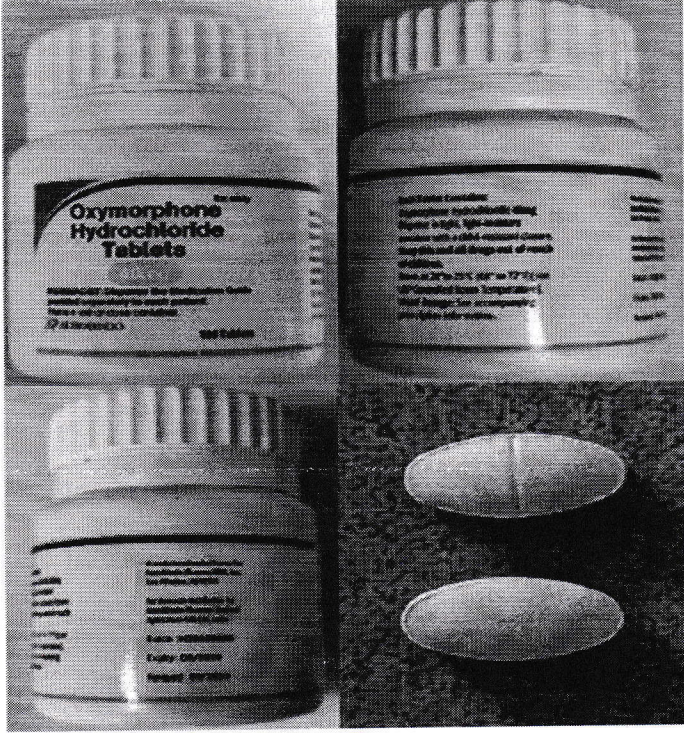
নং- ডিজিডিএ/ এলার্ট-নোটিশ/এমসি-১৬/২০১৯/ ২৪৬৪৬

অফিস আদেশ

তারিখঃ ২২/০৬/২০২৪ খ্রীঃ

ঔষধ প্রশাসন অধিদপ্তরের মাঠ পর্যায়ের সকল কর্মকর্তাদের জানানো যাচ্ছে যে, বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলার্ট 03/2024 এ এই মর্মে সতর্ক করেছে যে, ফিনল্যান্ডে অনিয়ন্ত্রিত সাপ্লাই চেইন থেকে Oxymorphone Hydrochloride 40mg এর একটি ব্যাচ নকল (falsified) হিসেবে শনাক্ত করা হয়েছে। Oxymorphone Hydrochloride 40mg নামীয় ঔষধটি মাঝারি থেকে তীব্র ব্যথার চিকিৎসায় ব্যবহৃত হয়। ঔষধটি ল্যাভে বিশ্লেষণ করা হলে এতে Oxymorphone Hydrochloride এর পরিবর্তে Metonitazene পাওয়া যায় বলে বিশ্ব স্বাস্থ্য সংস্থা (WHO) কে Finnish Medicines Agency (FIMEA) জানিয়েছে। Metonitazene একটি শক্তিশালী সাইকোট্রপিক সিন্থেটিক ওপিওয়েড ঔষধ যার কোনো স্বীকৃত ঔষধি ব্যবহার নেই এবং অল্প ডোজে গুরুতর পার্শ্ব প্রতিক্রিয়া ও ওভারডোজে প্রাণঘাতী হতে পারে। Oxymorphone Hydrochloride 40mg এর উৎপাদনকারক এবং বাজারজাতকারক AUROLIFE PHARMA LLC উক্ত ব্যাচটি নকল (falsified) এবং তাদের কর্তৃক উৎপাদিত নয় বলে নিশ্চিত করেছে।

**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    |  |

এমতাবস্থায় উল্লিখিত ব্যাচের Oxymorphone Hydrochloride 40mg পদটি বাজারে পাওয়া গেলে তা জব্দ করে প্রয়োজনীয় ব্যবস্থা গ্রহণের জন্য এতদ্বারা নির্দেশ প্রদান করা গেল।

২২/০৬/২৪  
আসরাফ হোসেন  
পরিচালক  
ও

হেড অব মার্কেট সার্ভিল্যান্স এন্ড কন্ট্রোল  
ঔষধ প্রশাসন অধিদপ্তর, ঢাকা।

ফোনঃ ০২২২২২-৮০৮০৩

## **Medical Product Alert No. 3/2024**

### **Falsified (contaminated) Oxymorphone Hydrochloride 40mg identified in the WHO Region for Europe**

#### **Alert Summary**

This WHO Medical Product Alert refers to one batch of falsified Oxymorphone Hydrochloride 40mg. The falsified product was detected in the unregulated supply chain in Finland and reported to WHO in July 2024 by the Finnish Medicines Agency (FIMEA).

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

Metonitazene is a potent psychoactive synthetic opioid drug, with no officially recognized or authorized medicinal or therapeutic use. It is under international control as a Schedule I narcotic drug following recommendations of the WHO Expert Committee on Drug Dependence in 2021. Small doses can result in serious adverse effects such as respiratory depression, severe sedation, addiction, and an overdose may be fatal.

#### **How to identify this falsified product**

This product is confirmed as falsified because it deliberately misrepresents its identity, composition, and source. The falsified product imitates Oxymorphone Hydrochloride marketed by AUROLIFE PHARMA LLC., who have confirmed that the product, subject of this Alert, is falsified and was not produced by their company.

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.

Please refer to the Annex of this Alert for full details of the falsified product.

#### **Risks**

This falsified product may have been intentionally designed to mimic products authorized by the U.S. Food and Drug Administration and marketed by AUROLIFE PHARMA LLC as Oxymorphone Hydrochloride. However, it contains undeclared metonitazene, which poses a significant risk to users due to the high likelihood of adverse events, even in small doses. Metonitazene produces effects similar to other opioids. Its high potency carries a high risk of overdose and death. Use of this falsified product may be life-threatening.

#### **Advice to healthcare professionals, regulatory authorities and the public**

Healthcare professionals should report any incident of adverse effects, lack of expected effects or suspected falsification to the National Regulatory Authorities/National Pharmacovigilance Centre.

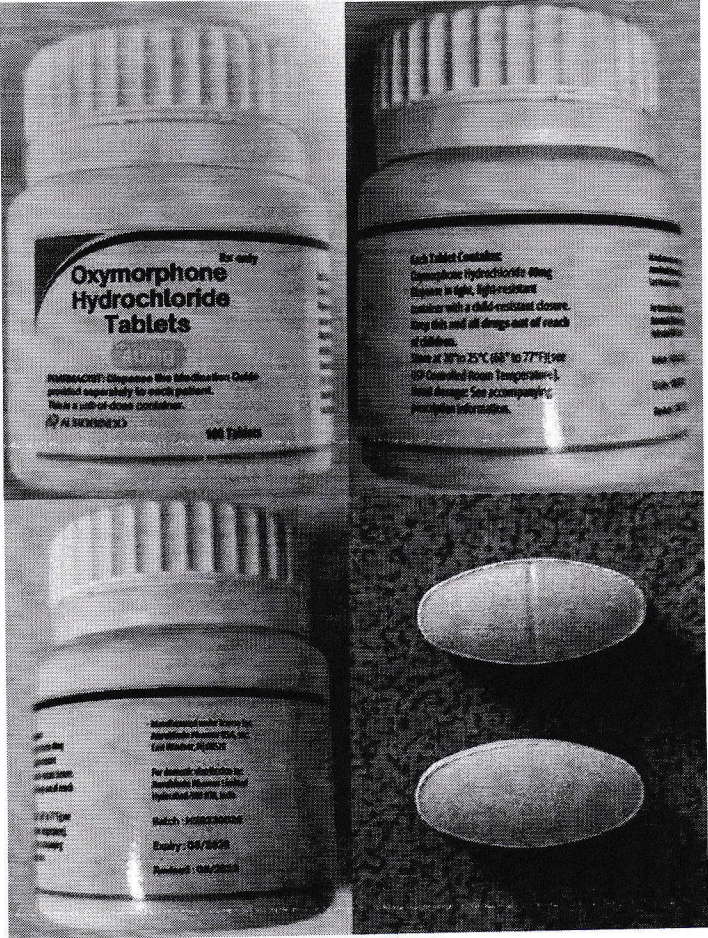
WHO advises increased surveillance and diligence within the supply chains of countries and regions likely to be affected by these falsified products. Increased surveillance of the informal/unregulated market is also advised. National

regulatory authorities/health authorities/law enforcement are advised to immediately notify WHO if the falsified product is detected in their country.

If you are in possession any of these products, WHO recommends that you do not use them. If you, or someone you know, has, or may have used these products, or suffered an adverse event or unexpected side-effect after use, seek immediate medical advice from a healthcare professional or contact a poisons control centre.

All medical products must be obtained from authorized/licensed suppliers. If you have any information about the manufacture or supply of these falsified products, please contact WHO via [rapidalert@who.int](mailto:rapidalert@who.int).

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

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