

Government of the People's Republic of Bangladesh  
Directorate General of Drug Administration  
Drug Bhavan, Mohakhali, Dhaka  
[www.dgda.gov.bd](http://www.dgda.gov.bd)

No-DGDA/Alert-Notice/MC-16/2019/13631

Date: 08/09/2025

**Office Order**

This is to notify that, the World Health Organization (WHO) has recently published a Medical Product Alert N°04/2025 about **FENTANILO HLB (fentanyl citrate)**, which is manufactured by **LABORATORIOUS RAMALLO S.A.** and marketing authorization is hold by **HLB Pharma Groups S.A.** This Alert refers to six lots/batches of substandard (contaminated) **FENTANILO HLB (fentanyl citrate)** injection 0.05mg/ml. The falsified product was detected in Argentina and reported to WHO in May 2025.

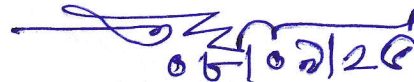
In May 2025, WHO identified a fatal outbreak of bacterial infections in Argentina linked to a contaminated lot (Lot 31202) of injectable FENTANILO HLB. The contamination involved the drug-resistant bacteria: *Klebsiella pneumoniae* and *Ralstonia picketti*. Information now available to WHO indicates that multiple Lots of FENTANILO HLB are now considered to be contaminated and are therefore subject to recall in Argentina by ANMAT (Argentine National Regulatory Authority).

**Annex: Product subject of WHO Product Alert No. 04/2025**

<b>Product Name</b>	FENTANILO HLB (Fentanilo Citrato) 0,05 mg/ml					
<b>Product registration holder</b>	HLB PHARMA GROUP S.A.					
<b>Stated manufacturer</b>	LABORATORIOS RAMALLO S.A					
<b>Lot</b>	31200	31202	31244	31245	31246	31247
<b>Identified in</b>	Argentina					
<b>Available Photographs</b>	No Available photographs.					

In such circumstances, if said lots/batches of the FENTANILO HLB (fentanyl citrate) 0.05 mg/ml are available in the market hereby ordered all the field level officers of the Directorate General of Drug Administration (DGDA) to seize and take necessary action.

Attachment: 02(Two) Pages



Ashraf Hossain  
Director &

Head of Market Surveillance and Control,  
Directorate General of Drug Administration (DGDA)  
Aushudh Bhaban, Mohakhali, Dhaka-1212

Mobile: 01819140421

Email: [dgda.gov@gmail.com](mailto:dgda.gov@gmail.com)

**Distribution:**

1. Head of Registration and Marketing Authorization (MA), DGDA
2. Head of Quality Management System (QMS), DGDA
3. Deputy Director, All Divisional Office (Request for Monitoring)
4. Deputy Chief, National Drug Control Laboratory, DGDA
5. Assistant Director/ Assistant Licensing Officer/ Superintendent of Drugs/ Inspector of Drugs, Divisional office /District office/Port office,....., DGDA

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No-DGDA/Alert-Notice/MC-16/2019 / 13632

Date: 08/09/2025

**Subject: Regarding the Medical Product Alert 04/2025 issued by the World Health Organization (WHO).**

This is to notify that, the World Health Organization (WHO) has recently published a Medical Product Alert N°04/2025 about **FENTANILO HLB (fentanyl citrate)**, which is manufactured by **LABORATORIOS RAMALLO S.A.** and marketing authorization is hold by **HLB Pharma Groups S.A.** This Alert refers to six lots/batches of substandard (contaminated) **FENTANILO HLB (fentanyl citrate)** injection 0.05mg/ml. The falsified product was detected in Argentina and reported to WHO in May 2025.


In May 2025, WHO identified a fatal outbreak of bacterial infections in Argentina linked to a contaminated lot (Lot 31202) of injectable FENTANILO HLB. The contamination involved the drug-resistant bacteria: *Klebsiella pneumoniae* and *Ralstonia picketti*. Information now available to WHO indicates that multiple Lots of FENTANILO HLB are now considered to be contaminated and are therefore subject to recall in Argentina by ANMAT (Argentine National Regulatory Authority).

**Annex: Product subject of WHO Product Alert No. 04/2025**

<b>Product Name</b>	FENTANILO HLB (Fentanilo Citrato) 0,05 mg/ml					
<b>Product registration holder</b>	HLB PHARMA GROUP S.A.					
<b>Stated manufacturer</b>	LABORATORIOS RAMALLO S.A					
<b>Lot</b>	31200	31202	31244	31245	31246	31247
<b>Identified in</b>	Argentina					
<b>Available Photographs</b>	No Available photographs.					

It is requested to refrain from using the said lots/batches of **Inj. FENTANILO HLB (Fentanyl Citrate) 0.05 mg/ml** and take necessary measures to be cautious in this regard.

Attachment: 02(Two) Pages



Ashraf Hossain  
Director &

Head of Market Surveillance and Control,  
Directorate General of Drug Administration (DGDA)  
Aushudh Bhaban, Mohakhali, Dhaka-1212

Mobile: 01819140421

Email: [dgda.gov@gmail.com](mailto:dgda.gov@gmail.com)

Distribution (not in order of seniority):

1. Director General, Directorate General of Health Services
2. Director, CMSD, Tejgaon, Dhaka
3. AIG (NCB), Police Head Quarter, Dhaka
4. Civil Surgeon, All Civil Surgeon Offices, DGHS
5. Secretary General, Bangladesh Association of Pharmaceutical Industry (BAPI)
6. President / General Secretary, Bangladesh Medical Association (BMA)
7. President, Bangladesh Chemist and Druggist Somity (BCDS) (Request for stop sale, stock, distribution or exhibition of this drug).

## Medical Product Alert N°4/2025

### Substandard (contaminated) FENTANILO HLB (fentanyl citrate) identified in the WHO Region of the Americas

#### Alert Summary

This WHO Medical Product Alert concerns substandard FENTANILO HLB (fentanyl citrate) detected in Argentina.

Fentanyl citrate injections are opioid analgesics used to relieve pain during and after surgery. It is also used to reduce the rate of breathing in patients who are on a ventilator. It is also used to manage severe pain in patients with chronic conditions.

In May 2025, WHO identified a fatal outbreak of bacterial infections in Argentina linked to a contaminated lot (Lot 31202) of injectable FENTANILO HLB. The contamination involved the drug-resistant bacteria: *Klebsiella pneumoniae* and *Ralstonia Picketti*.

Information now available to WHO indicates that multiple Lots of FENTANILO HLB are now considered to be contaminated and are therefore subject to recall in Argentina.

On 13 May 2025 the Argentine national regulatory authority ANMAT, issued an alert and recall for FENTANILO HLB - Lot 31202 which had tested positive for *Klebsiella pneumoniae* and *Ralstonia Picketti*. The ANMAT Alert makes clear that while HLB PHARMA GROUP S.A. holds the marketing authorization to FENTANILO HLB in Argentina, the actual manufacturing was contracted to another company; LABORATORIOS RAMALLO S.A.

On 24 Feb 2025 ANMAT had suspended the manufacturing activities of LABORATORIOS RAMALLO S.A. for significant deficiencies, classified as critical and serious, across several operational areas, including failures in ensuring product safety and efficacy. On 13 May 2025, ANMAT prohibited the use, distribution, and marketing of all HLB PHARMA products on the market in Argentina. ANMAT issued other alerts and recalls for substandard products produced or distributed by HLB PHARMA. However, substandard products manufactured by LABORATORIOS RAMALLO S.A. and or HLB PHARMA may still be in circulation.

Given the serious deficiencies in Good Manufacturing Practice identified by ANMAT, any injectable or parenteral product manufactured or distributed by LABORATORIOS RAMALLO S.A. or HLB PHARMA after February 2022 should be treated with caution. These products may pose a risk of being contaminated, and their use could compromise patient safety. Caution is strongly advised until verification of the products quality is confirmed.

The products identified in this Alert are considered substandard as they fail to meet either their quality standards or specifications, and are, therefore "out of specification".

#### How to identify these falsified products

See Annex with list of affected Lots.

**Risks**

FENTANILO HLB (fentanyl citrate) is administered by injection. It may likely be given to critically ill or surgical patients. Such patients may already be vulnerable. Because of this the products sterility and quality are critical to patient safety.

The sterility of the FENTANILO HLB products identified in this WHO Medical Product Alert are considered compromised, as they may be contaminated with *Klebsiella pneumoniae* and or *Ralstonia pickettii*.

These contaminated products pose significant risks to patients and can cause severe and potentially life-threatening infections, particularly in vulnerable individuals. Any use of these products poses a high risk to patients.

To protect patients, it is essential to detect and remove these substandard products from circulation.

**Advice to health-care professionals, regulatory authorities and the public**

Health-care professionals should report the detection of these substandard products and any incident of adverse effects, lack of expected effects to their National Regulatory Authorities or National Pharmacovigilance Centre.

WHO advises increased surveillance and diligence within the supply chains of countries and regions likely to be affected by these substandard 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 of 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 health-care 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 N°4 /2025**

<b>Product Name</b>	FENTANILO HLB (fentanilo citrato) 0,05 mg/ml					
<b>Product registration holder</b>	HLB PHARMA GROUP S.A.					
<b>Stated manufacturer</b>	LABORATORIOS RAMALLO S.A					
<b>Lot</b>	31200	31202	31244	31245	31246	31247
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