29 August 2025

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 use 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.

Annex: Products subject of WHO Medical Product Alert N°4 /2025

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