



20, AVENUE APPIA - CH-1211 GENEVA 27 - SWITZERLAND - TEL CENTRAL +41 22 791 2111 - FAX CENTRAL +41 22 791 3111 - WWW.WHO INT

RPQ/REG/ISF/Alert N°5/2022

25 August 2022

## Medical Product Alert N°5/2022

## Falsified DIPRIVAN (Propofol) identified in WHO region of the Americas

Alert Summary

This WHO Medical Product Alert refers to falsified DIPRIVAN (propofol), identified in Venezuela (Bolivarian Republic of) in July 2022 and reported to WHO in August 2022.

DIPRIVAN is indicated for use as a short-acting intravenous general anaesthetic during diagnostic and surgical procedures, and for the sedation of ventilated patients.

Genuine DIPRIVAN is manufactured by ASTRAZENECA for ASPEN. Both ASPEN and ASTRAZENECA have confirmed that the products referenced in this Alert are falsified on the basis that they deliberately/fraudulently misrepresent their identity and source.

DIPRIVAN is manufactured for the Latin American market and is authorized for local use by several countries including Colombia, Dominican Rep, and Ecuador.

The stated Lot numbers are falsified and have never been issued for DIPRIVAN.

Printing and spelling errors have also been identified and the fill line is potentially inconsistent among the identified vials.

## Risks

The safety, sterility and quality of the falsified products referenced in this alert are unknown.

DIPRIVAN is administered intravenously and used to sedate patients. These falsified products may therefore pose a particular high risk to patients.

It is important to detect and remove these falsified products from circulation to prevent harm to patients.

Advice to regulatory authorities and the public

WHO requests increased surveillance and diligence within the supply chains of countries and regions likely to be affected by these falsified products.

All medical products must be approved and obtained from authorized/licensed suppliers. The products' authenticity and physical condition should be carefully checked. Seek advice from a healthcare professional when in doubt.

If you are in possession of these falsified products, please do not use them.

If you have used these products, or you suffered an adverse reaction/event after use, you are advised to seek immediate medical advice from a qualified healthcare professional and report the incident to the National Regulatory Authority or National Pharmacovigilance Centre.

National regulatory/health authorities are advised to immediately notify WHO if these falsified products are discovered in their country.

If you have any information concerning the manufacture or supply of these products, please contact WHO via rapidalert@who.int

Please see annex for details and photos of the falsified products referenced in Alert N°5/2022.



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## Table 1: Products subject of WHO Medical Product Alert N°5/2022

Available Photos		Identified in	Packaging language	Lot number	Stated manufacturer	Product Name
TOTAL COST SOLITOR OF THE PROPERTY OF THE PROP	Later reported to a Zime Extra on people of Finding 20 ml 1	Venezuela (Bolivarian Republic of)	Spanish	FB932	AstraZeneca	DIPRIVAN 10mg/ml
(ZOERO 8 3163) CSUR 90 81 SEE 81 3 101	10 m	Venezuela (Bolivarian Republic of)	Spanish	FB825	AstraZeneca	DIPRIVAN 10mg/ml

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products For more information, please visit our website. Email: rapidalert@who.int

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