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Ref. RPQ/REG/ISF/Alert N°3/2022 27 May 2022

Medical Product Alert

Falsified Intratect (Human normal immunoglobulin) identified in the WHO Regions of the Americas, Eastern Mediterranean and South-East Asia

Alert Summary

This WHO Medical Product Alert refers to four falsified lots of Intratect reported from Brazil (September 2021), India (February 2022), Bolivia (Plurinational State of) (April 2022) and Egypt (April 2022).

Genuine Intratect contains human normal immunoglobulin which is used to treat patients who do not have sufficient antibodies (replacement therapy) or to treat patients with certain inflammatory disorders (immunomodulation).

The genuine manufacturer of Intratect is Biotest GmbH, who have confirmed that all the products referenced in this alert are falsified, including those labelled “Immunoglobulina G Endovenosa Biotest”. Biotest GmbH does not manufacture any products with this name. The stated lot numbers are also confirmed as falsified.

The products identified in this alert are falsified on the basis that they deliberately/fraudulently misrepresent their identity, and source. Their safety and efficacy are unknown.

Risks

Genuine Intratect is administered intravenously. Healthcare professionals should carefully observe administration/infusion to make sure that the rate of infusion is within a clinically acceptable range and that the patient does not suffer an adverse reaction.

Although laboratory analysis of these falsified products has not been completed, they may pose a particular risk to patients as they are administered intravenously and their sterility, effectiveness and safety are unknown.

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 and/or distribution of these products, please inform WHO via rapidalert@who.int

Please see page 2 for the list of falsified products

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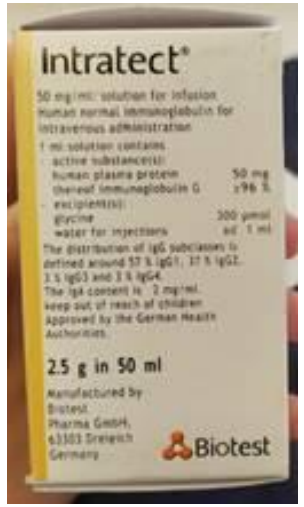
Product Name	**Immunoglobulina G Endovenosa Biotest**	**Immunoglobulina G Endovenosa Biotest**	**INTRATECT 100g/l solution for infusion(10%)**	**INTRATECT 2.5 g/50 mL**
Stated manufacturer	Biotest Pharma GmbH	Biotest Pharma GmbH	Biotest Pharma GmbH	Biotest Pharma GmbH
Lot	ID 05 G 20050	3C30000087	C146181P02	B842961
Mfg. date	unknown	07/2020	05/2021	01/2021
Exp. date	unknown	05/2022	04/2023	08/2023
Packaging language	Spanish	Spanish	English	English
Identified in	BOLIVIA (PLURINATIONAL STATE OF)	BRAZIL	INDIA	EGYPT
Available photo				

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products

For more information, please visit our website. Email: rapidalert@who.int