Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

**FDA ADVISORY**
No. 2022-1177

16 JUN 2022

**TO:** **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

**SUBJECT:** **Public Health Warning on Falsified Drug Product "Intratect" Confirmed by the World Health Organization (WHO)**

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The Food and Drug Administration (FDA) notifies the public on the WHO Medical Product Alert on four (4) falsified Human Normal Immunoglobulin Solution with brand name "Intratect" which were detected in the Americas, Eastern Mediterranean, and South-East Asia regions from September 2021 to April 2022:

| PRODUCT NAME | Immunoglobulina G Endovenosa Biotest | Immunoglobulina G Endovenosa Biotest |
|---|---|---|
| STATED MANUFACTURER | Biotest Pharma GmbH | Biotest Pharma GmbH |
| LOT | ID 05 G 20050 | 3C30000087 |
| MFG. DATE | unknown | 07/2020 |
| EXP. DATE | unknown | 05/2022 |
| PACKAGING LANGUAGE | Spanish | Spanish |
| IDENTIFIED IN | Bolivia (Plurinational State of) | Brazil |
| AVAILABLE PHOTO |   |   |

Figure 1. Human Normal Immunoglobulin [Intratect] detected in Bolivia and Brazil

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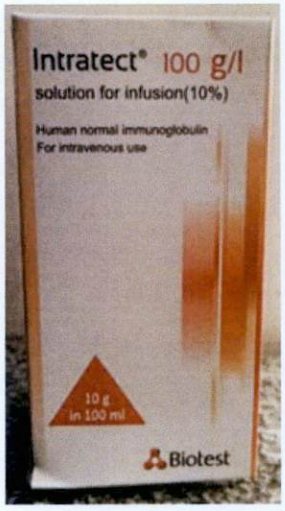
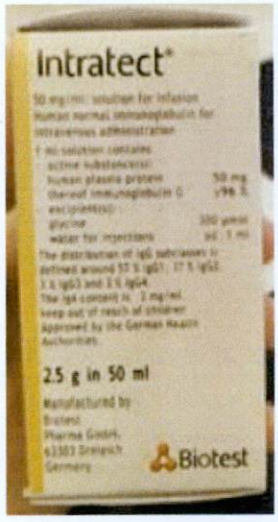
| PRODUCT NAME | INTRATEC 100 g/l Solution for Infusion (10%) | INTRATEC 2.5 g/50 mL |
|---|---|---|
| STATED MANUFACTURER | Biotest Pharma GmbH | Biotest Pharma GmbH |
| LOT | C146181P02 | B842961 |
| MFG. DATE | 05/2021 | 01/2021 |
| EXP. DATE | 04/2023 | 08/2023 |
| PACKAGING LANGUAGE | English | English |
| IDENTIFIED IN | India | Egypt |
| AVAILABLE PHOTO |   |   |

Figure 2. Human Normal Immunoglobulin [Intratect] detected in India and Egypt

The FDA strongly advises the public to be vigilant on the circulation of this falsified drug product since this poses a particular risk to patients as they are administered intravenously, and their sterility, effectiveness, and safety are unknown. A falsified drug product deliberately or fraudulently misrepresents its identity, composition, or source. Their safety and efficacy are unknown. The genuine manufacturer, Biotest Pharma GmbH, confirmed that all the products and lot numbers referenced are falsified, including those labelled as "Immunoglobulina G Endevenosa Biotest", were not manufactured by Biotest.

This is to emphasize that Human Normal Immunoglobulin 100 g/l Solution for Infusion (10%) [Intratect] is not registered with FDA. Authentic Intratec is used to treat patients who do not have sufficient antibodies (replacement therapy) or to treat patients with certain inflammatory disorders (immunomodulation).

Therefore, all Local Government Units (LGU) and Law Enforcement Agencies (LEAs), after the issuance of this advisory, are requested to ensure that this falsified drug product is not sold or not administered to patients in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report unauthorized sale, or distribution of the abovementioned, kindly e-mail us via **cdrr.od@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**.

Dissemination of the information to all concerned is highly requested.

**DR. OSCAR G. GUTIERREZ, JR.**
Officer-in-Charge Director General

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