Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No: 2022-1498

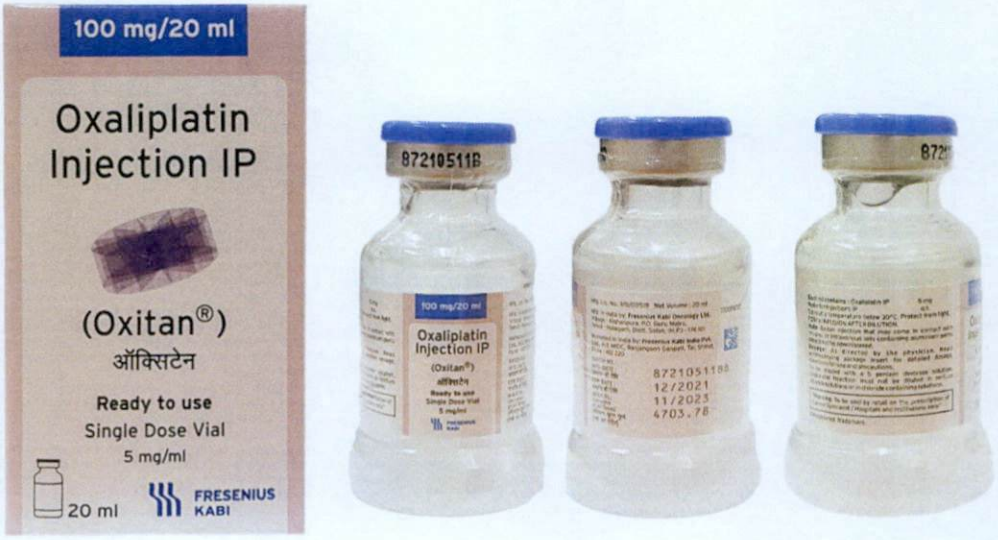
25 AUG 2022

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

SUBJECT : **Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:**

1. **Fresenius Kabi Oxaliplatin Injection I.P. Oxitan® Single Dose Vial 5 mg/mL (100mg/ 20mL) 20 mL**
2. **Natco Imatinib Tablets I.P. Veenat® 400 3 x 10 Tablets**
3. **Dem Ilac Thromboreductin® 0,5 Kapsul 100's**

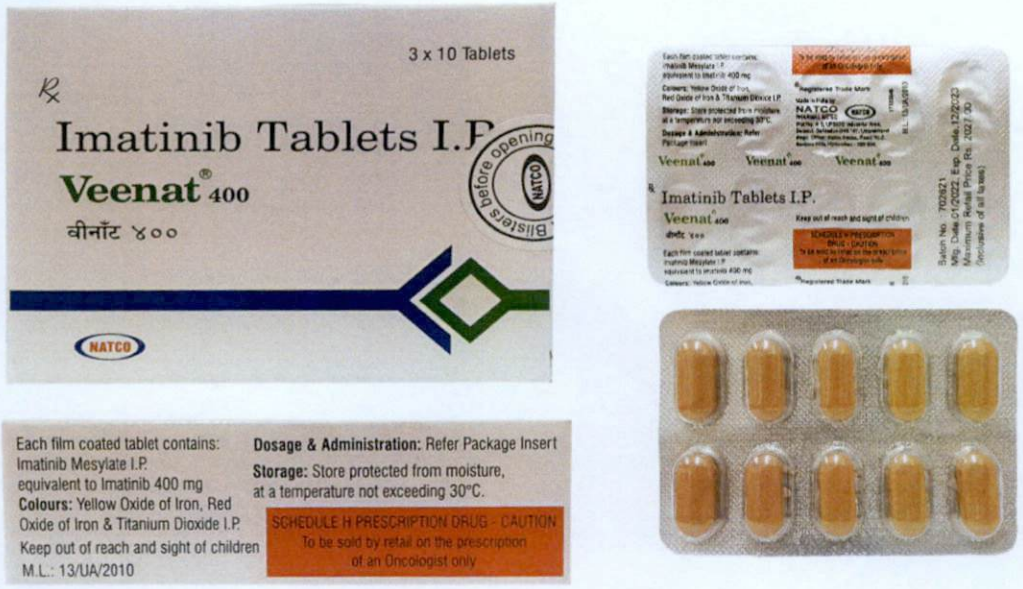
The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products:



Fresenius Kabi Oxaliplatin Injection I.P. Oxitan® Single Dose Vial 5 mg/mL (100mg/ 20mL) 20 mL

Manufactured by: Fresenius Kabi Oncology Ltd. Village – Kishanpura, P.O. Guru Majra, Tehsil – Nalagarh, Dist. Solan, (H.P.) – 174 101 Marketed by: Fresenius Kabi India Pvt. Ltd. – A-3, MIDC, Ranjangaon Ganpati, Tal. Shirur, Pune – 412 220Square, 127, Andheri-Kurla Road, Andheri (East) Mumbai - 400 069 India

Figure 1. Unregistered drug product



Natco Imatinib Tablets I.P. Veenat® 400 3 x 10 Tablets

by: Natco Pharma Limited – Plot No. A-3, UPSIDC Industrial Area, Selaqui, Dehradun-248 197, Uttarakhand. Regd. Office: Natco House, Road No. S2, Banjara Hills, Hyderabad – 500 034

Figure 2. Unregistered drug product

Dem Ilac Thromboreductin® 0,5 Kapsul 100's

Figure 3. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the Agency and have not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee their quality, safety and efficacy. Therefore, consumption of such violative products may pose potential danger or injury to health.

Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if the products are registered with the FDA by using the **FDA Verification Portal feature** accessible at **https://verification.fda.gov.ph.**

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **info@fda.gov.ph**. To report continuous sale or distribution of unregistered health products, kindly e-mail us via **ereport@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

DR. SAMUEL A. ZACATE
Director General

DTN: 20220811152519