



**FDA ADVISORY**  
No: **2022-1498**

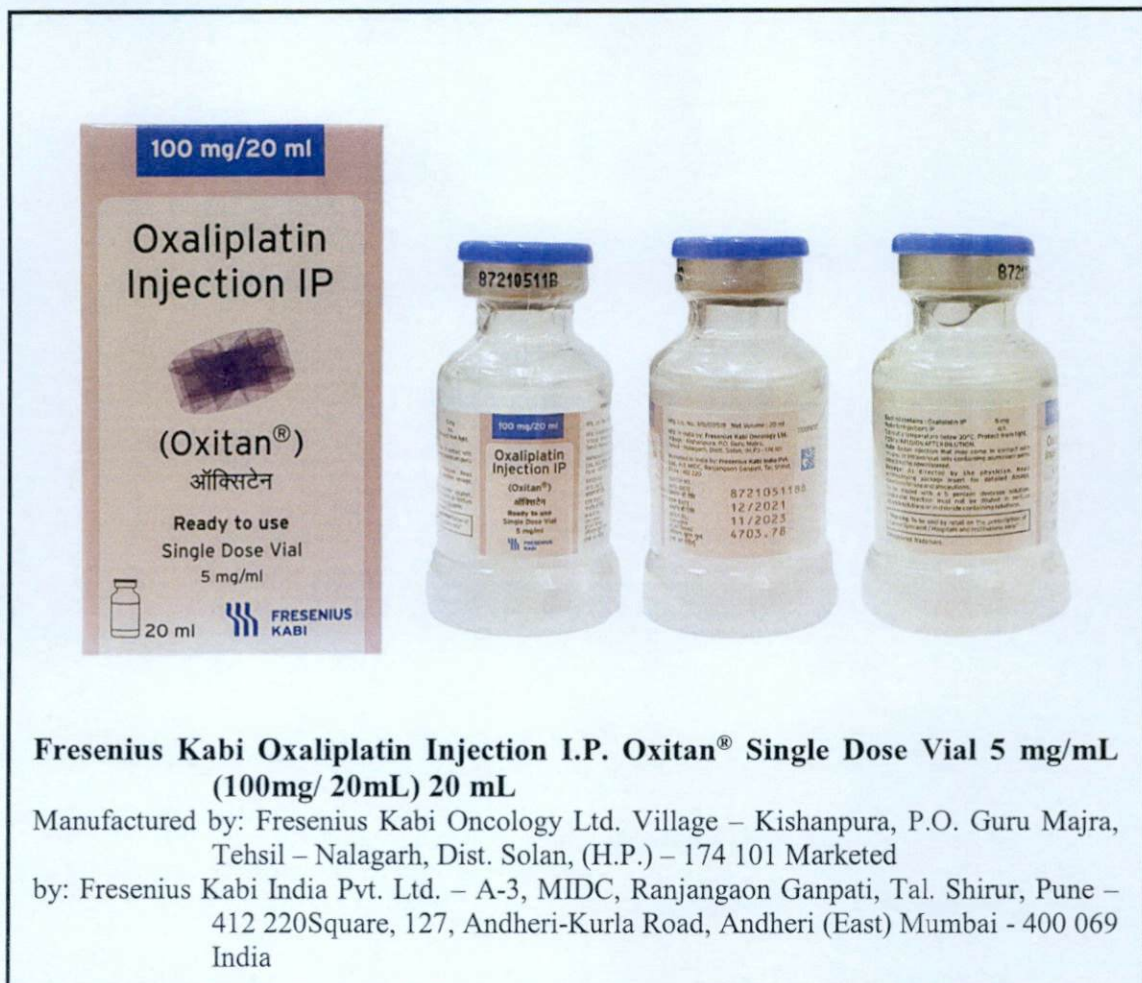
25 AUG 2022

**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 – 412 220 Square, 127, Andheri-Kurla Road, Andheri (East) Mumbai - 400 069 India

Figure 1. Unregistered drug product





3 x 10 Tablets

**Imatinib Tablets I.P.**

**Veenat<sup>®</sup> 400**

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NATCO



**Imatinib Tablets I.P.**

**Veenat<sup>®</sup> 400**

Each film coated tablet contains: Imatinib Mesylate I.P. equivalent to Imatinib 400 mg  
**Colours:** Yellow Oxide of Iron, Red Oxide of Iron & Titanium Dioxide I.P.  
 Keep out of reach and sight of children  
 M.L.: 13/UA/2010

**Dosage & Administration:** Refer Package Insert  
**Storage:** Store protected from moisture, at a temperature not exceeding 30°C.

**SCHEDULE H PRESCRIPTION DRUG - CAUTION**  
 To be sold by retail on the prescription of an Oncologist only

**Natco Imatinib Tablets I.P. Veenat<sup>®</sup> 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

**Thromboreductin<sup>®</sup>**  
 0,5 mg Kapsül

**Etken Madde:**  
 Her kapsül 0,5 mg anagrelid eşdeğer 0,57 mg anagrelid hidroklorür içerir.

**Yardımcı maddeler:**  
 Laktoz monohidrat (İlave bilgi için kullanma talimatına bakınız.)

**100 Kapsül**



Ruhsat Sahibi:  
 Dem İlaç Sanayi ve Ticaret A.Ş.  
 Dem Plaza İnönü Mah.  
 Kayışdağı Cad. No:  
 172 34755 Ataşehir-İstanbul

Üretim Yeri:  
 Haupt Pharma  
 Wolfratshausen GmbH  
 82515 Wolfratshausen  
 Almanya



Kullanma talimatını okumadan araç/makine kullanmayınız.

  
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**Thromboreductin<sup>®</sup>**  
**0,5 mg Kapsül 100 Kapsül**  
 Etken Madde: Her kapsül 0,5 mg anagrelid eşdeğer 0,57 mg anagrelid hidroklorür içerir.  
 Yardımcı maddeler: Laktoz monohidrat (İlave bilgi için kullanma talimatına bakınız.)  
 Reçete ile satılır. Çocukların göremeyeceği, erişemeyeceği yerlerde ve ambalajında saklayınız.  
 Üretim Yeri: Haupt Pharma Wolfratshausen GmbH, 82515 Wolfratshausen - Almanya  
 Ruhsat numarası: 04.01.2006-L

Ağızdan alınır. Orijinal ambalajında saklayınız. Kesilmiş veya açılmış ambalajları satın almayınız. 25°C altındaki oda sıcaklığında saklayınız.  
 Ruhsat Sahibi: Dem İlaç Sanayi ve Ticaret A.Ş., Dem Plaza İnönü Mah. Kayışdağı Cad., No:172 34755 Ataşehir-İstanbul  
 Dem İlaç

**Dem İlaç Thromboreductin<sup>®</sup> 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](mailto:info@fda.gov.ph). To report continuous sale or distribution of unregistered health products, kindly e-mail us via [ereport@fda.gov.ph](mailto: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.

DTN: 

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**DR. SAMUEL A. ZACATE**  
Director General