



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2022-1499**

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. Anastrozole Tablets IP Femistra™ 1 x 10 Tablets
2. Aprazer Capecitabine Tablets IP 500 mg Capekast™ 5x10 Tablets
3. Natco Imatinib Capsules I.P. Veenat® 100 120 Capsules

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

Anastrozole Tablets IP Femistra™
फेमिस्ट्रा

To report adverse events, call toll free on 1800 419 1141 or visit www.zyduscadila.com

Anastrozole Tablets IP Femistra™
फेमिस्ट्रा

Each film coated tablet contains:
Anastrozole IP 1 mg
Excipients q.s.
Colour: Titanium Dioxide IP

Keep in a cool dry place
Dosage: As directed by the Physician
Keep out of reach of children

CAUTION: Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Batch No. : M102518
Mfg. Date : 02 / 2021
Expiry Date : 01 / 2023
Maximum Retail Price ₹ : 366.81
Per 10 Tablets (Inclusive of All Taxes)

Mfg. Lic. No.: G/1486
Zydus Celexa Marketed by: Zydus Celexa (A division of Cadila Healthcare Ltd.)
Manufactured by: **Cadila Healthcare Ltd.**
Survey No. 417, 419 and 420, Sarkhej Bavla N.H. No. 8 A, Village: Moraiya, Tal.: Sanand, Dist.: Ahmedabad-382 210.
TM-Trademark applied for

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Anastrozole Tablets IP Femistra™ 1 x 10 Tablets
Manufactured by: Cadila Healthcare Ltd. - Survey No. 417, 419 and 420, Sarkhej Bavla N/H. No. 8 A, Village: Moraiya, Tal.: Sanand, Dist.: Ahmedabad-382 210.
by: Zydus Calexa (A division of Cadila Healthcare Ltd.)

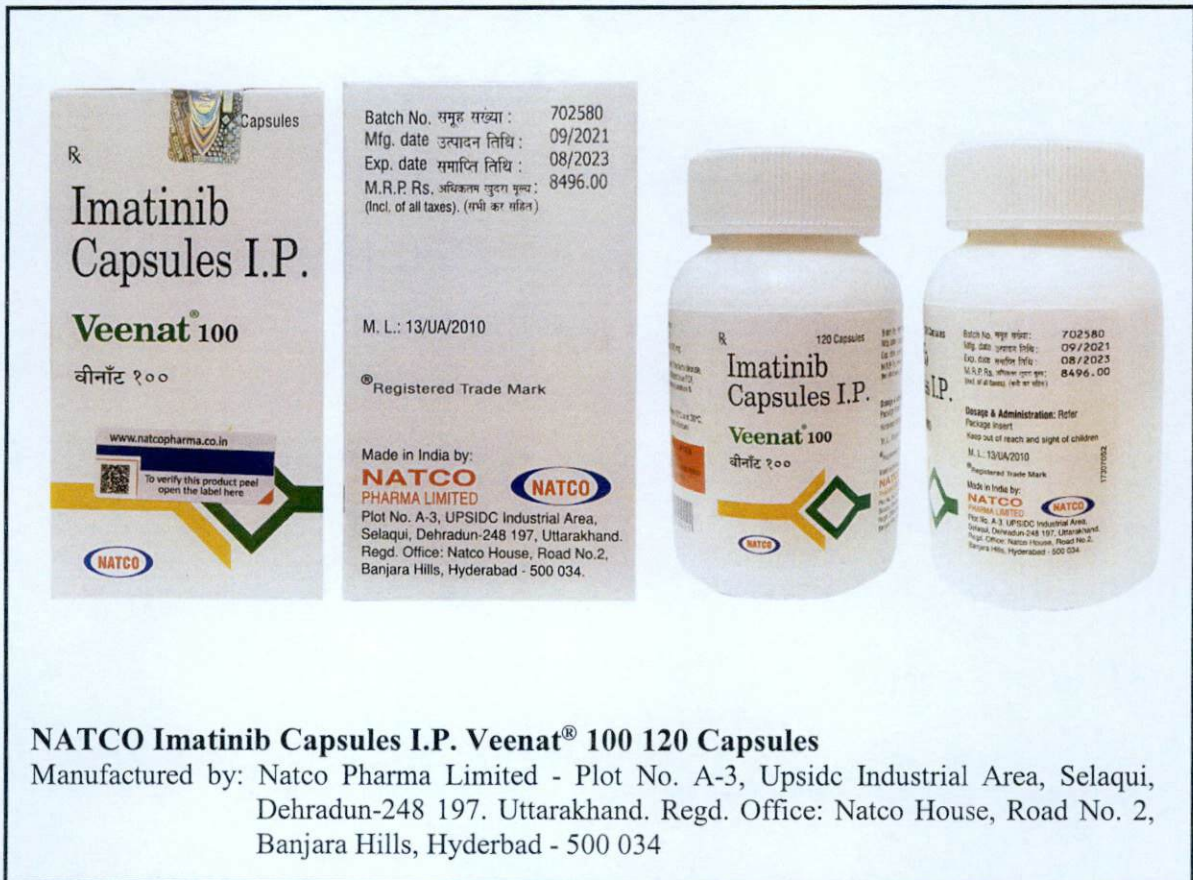
Figure 1. Unregistered drug product





Aprazer Capecitabine Tablets IP 500 mg Capekast™ 5x10 Tablets
 Manufactured by: Aprazer Healthcare Pvt. Ltd.
 by: Aprazer

Figure 2. Unregistered drug product



NATCO Imatinib Capsules I.P. Veenat® 100 120 Capsules
 Manufactured by: Natco Pharma Limited - Plot No. A-3, Upside Industrial Area, Selaqui, Dehradun-248 197, Uttarakhand. Regd. Office: Natco House, Road No. 2, Banjara Hills, Hyderabad - 500 034

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: 

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