

Republic of the Philippines Department of Health

FOOD AND DRUG ADMINISTRATION



FDA ADVISORY 2022-1556

2 5 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. Natco Zolendronic Acid Injection I.P. Zoldronat® 4mg/Vial for Intravenous Infusion Sterile, Lyophilized 1 Vial

2. Oncology Pazopanib Tablets 400 mg Pazinib[®] 400 mg 30

3. Natco Sutinib Malate Capsules Sutinat*12.5 28 Capsules

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



Natco Zolendronic Acid Injection I.P. Zoldronat® 4mg/Vial for Intravenous Infusion Sterile, Lyophilized 1 Vial

Manufactured: Natco Pharma Limited - Nagarjunasagar - 508 202 Regd. Office: Natco House, Road No. 2, Banjara Hills, Hyderabad-500 034

Figure 1. Unregistered drug product





Oncology Pazopanib Tablets 400 mg Pazinib[®] 400 mg 30 Tablets

Manufactured & Marketed by: Hetero Healthcare Limited – AIIDC Industrial Growth Centre, Changsari, Niz Sindurighpa (Village) Sila Sindurighopa (Mouza), Kamrup (Dist.), Assam - 781101

Figure 2. Unregistered drug product



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.

DTN:

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