



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



24 JAN 2022

FDA ADVISORY

No. **20220043**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. Baricitinib Tablets 4 mg Barinat * 4
2. Laroscorbine Platinum E-UF PN® 5 mL
3. NC24 Ultra PDRN Miracle 280000 Ultra Concentrated
Vial: Glutathione (280:1 /1,000mg) 280, 000mg
PDRN (Polydeoxyribonucleotide) 700mg I.M. /I.V.
Ampoule (10 mL): Refined Cranberry Extract (Plus Ascorbic Acid) 5,500 mg Thiocetic acid 2,400 mg Fibroblast Growth Factor FGF 2,250 mg
Ampoule (5 mL): DNA CollaPro 1500 mg Coenzyme Q10 CoQ10 1,800mg 5 mL

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



14 Tablets

Rx

Baricitinib
Tablets 4 mg

Barinat * 4
बारिनाट ४

Each film coated tablet contains:
Baricitinib 4 mg

Colours: Red Oxide of Iron, Yellow Oxide of Iron and Titanium Dioxide I.P.

Dosage: As directed by the physician.

Read package Insert before use.

Storage: Store below 30°C.

Keep out of reach of children.

Warning: To be sold by retail on the prescription of Specialist for use in Hospital / Institutional set up only.

Batch No. मूळ संख्या : 410900
Mfg. Date: तयार करीलेली दिनांक : 05/2021
Exp. Date: शेवटचा वापर करीलेली दिनांक : 04/2023
M.R.P. Rs. अधिकतम विक्रीचा दर : 419.00
(Incl. of all taxes) (सह कर सहित)

* Trade Mark pending

M. L.: 164/MN/AP/95/F/R

Made in India by:
NATCO PHARMA LIMITED
Pharma Division, Kothur (CT) (V), Kothur (M),
Ranga Reddy (D), Telangana State, India.
PIN - 509 228.
Regd. Office: Natco House, Road No.2,
Banjara Hills, Hyderabad - 500 034.



14 Tablets

Rx

Baricitinib
Tablets 4 mg

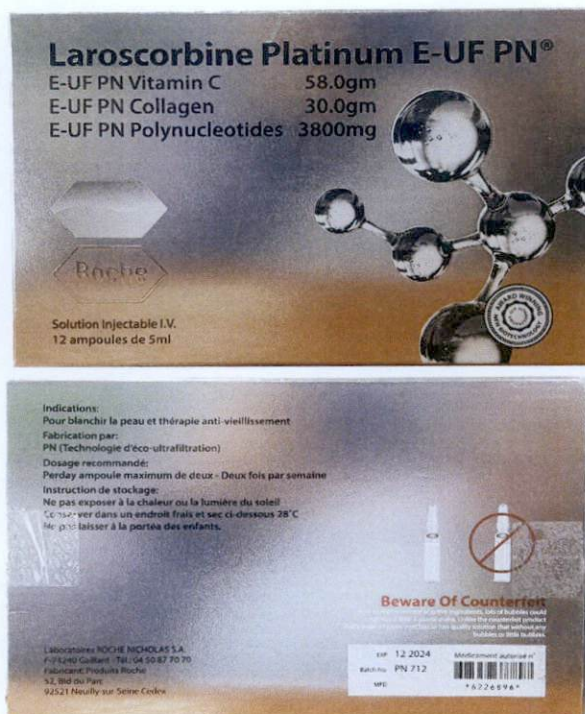
Barinat * 4
बारिनाट ४

Baricitinib Tablets 4 mg Barinat * 4

Manufactured by: Natco Pharma Limited – Pharma Division, Kothur (CT) (V), Kothur (M), Ranga Reddy (D), Telangana State, India

Figure 1. Unregistered drug





Laroscorbine Platinum E-UF PN® 5 mL
by: Laboratoires Roche Nicholas S.A.F F-74240 Gaillard

Figure 2. Unregistered drug



Vial: Glutathione
(280:1 / 1,000mg)
280,000mg PDRN
(Polydeoxyribonucleotid)
700mg I.M./I.V.

Ampoule (10 mL): Refined
Cranberry Extract (Plus
Ascorbic Acid) 5,500 mg
Thioctic acid 2,400 mg
Fibroblast Growth Factor FGF
2,250 mg

Ampoule (5 mL):
DNA CollaPro 1500 mg
Coenzyme Q10 CoQ10
1,800mg 5 mL

NC24 Ultra PDRN Miracle 280000 Ultra Concentrated

Figure 3. Unregistered drug

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

DTN:



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