



03 FEB 2022

FDA ADVISORY
No. **2022-0069**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

- 1. Piracetam Tablets 800 mg. Piratican 800**
- 2. Anastrozole Tablets IP 1 mg Anaridex® 1x10 Tablets**
- 3. Bimatoprost Ophthalmic Solution 0.03% w/v Bimat Eye Drops 3 mL**

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



Piracetam Tablets 800 mg. Piratican 800

Manufactured by: Elikem Pharmaceutical Private Limited - 816/1, Ta. Kaloi, Dist. Gandhinagar, Guj, 382721

Manufactured for: American Remedies Healthcare Pvt. Ltd. - 307, Gundecha Ind. Complex, Akurli Road, Kandivali East, Mumbai - 400 101, Maharashtra, India

Figure 1. Unregistered drug



1 X 10 Tablets

Anastrozole Tablets IP 1 mg
Anaridex[®]
1mg

Healing Pharma
Your health is our goal

Composition:
Each film coated tablet contains:
Anastrozole IP 1 mg
Excipients Q.S.
Colour: Titanium Dioxide IP
Dosage: As directed by the physician
Keep medicine out of reach of children.
Storage: Store in a cool, dry place & below 30°C temperature, protect from light.
Warning: To be sold by retail on the prescription of a registered medical practitioner only.

Marketed by:
Healing Pharma
Healing Pharma India Pvt. Ltd.
B-411, Eastern Edge II Premises CHS Ltd, Near Metro Mall, Western Express Highway, Borivali (East) Mumbai - 400066
International Correspondence Office: Healing Pharma LLC, DE USA
® - Registered Trade Mark

Mfg. Lic. No.: G/25/1428
B. NO. ST-3714
M. D. 04/21
E. D. 03/23
MRP RS: 450.00 1AT



Anastrozole Tablets IP 1 mg Anaridex[®] 1x10 Tablets

Manufactured by: Sunrise Remedies Pvt. Ltd. – Block No. 2244, Opp. Shah Alloys Santej, Ta. Kalol, Dist. Gandhinagar, (Guj.)

Marketed by: Healing[®] Pharma India Pvt. Ltd. - B-411, Eastern Edge II Premises CHS Ltd, Near Metro Mall, Western Express Highway, Borivali (East), Mumbai-400066

Figure 2. Unregistered drug

3 ml

Bimatoprost Ophthalmic Solution
0.03% w/v

BIMAT
Eye Drops

Sterile **ajanta**

FOR EXTERNAL USE ONLY.
NOT FOR INJECTION.

DIRECTION FOR USE :
Turn the pufferproof cap anti-clockwise to break the seal.
Remove the cap, dispense drops with gentle pressure.
Replace the cap after every use.

M. L. No. : 395/DR/Mfg./2017
Manufactured in India by :
ajanta pharma limited
Mid. at. Mirza-Palashbari Road, Village Kokjhar, Kamrup (R), Guwahati, Assam - 781128.
Regd Office: Ajanta House, Charkop, Kandivli (W), Mumbai 400 067.

Bimatoprost Ophthalmic Solution 0.03% w/v Bimat Eye Drops 3 mL

Manufactured by: Ajanta Pharma Limited - Mirza-Palashbari Road, Village Kokjhar, Kamrup (R), Guwahati, Assam - 781128, Regd Office: Ajanta House, Charkop, Kandivli (W), Mumbai 400067

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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