Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

24 JAN 2022

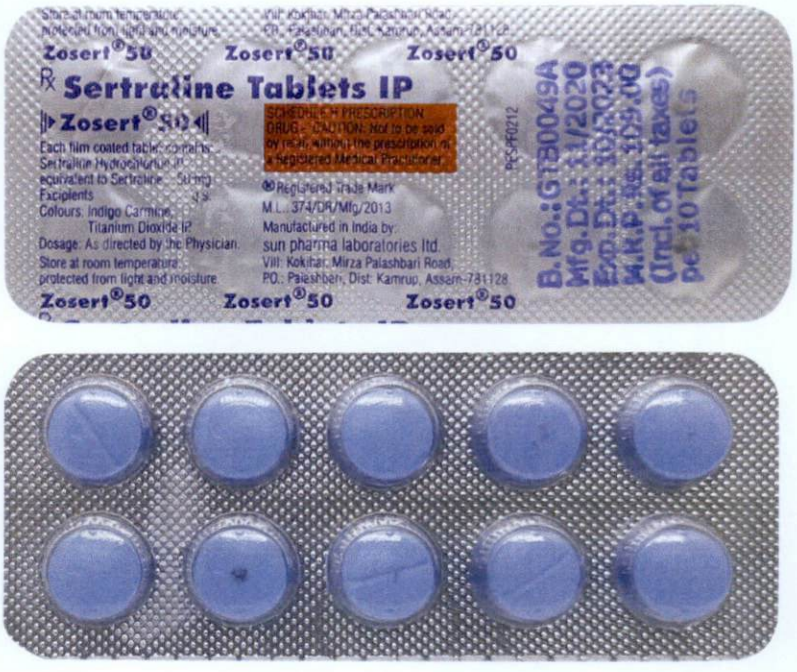
FDA ADVISORY
No. 20220044

TO : **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

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

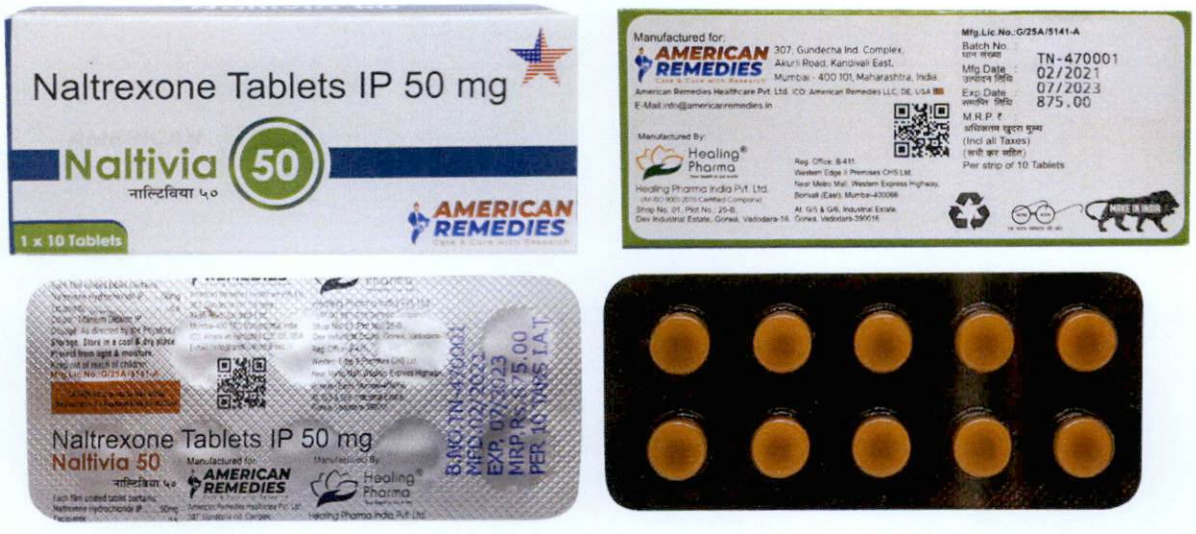
1. **Sertraline Tablets IP (Zosert® 50) 50 mg**
2. **Naltrexone Tablets IP 50 mg Naltivia 50 1x10 Tablets**
3. **Mogadon® 5 mg (Nitrazepam) Tablet**

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



Sertraline Tablets IP (Zosert® 50) 50 mg
Manufactured in India by: Sun Pharma Laboratories Ltd. - Vill Kokjhar, Mirza Palashbari Road, P.O: Palashbari, Dist: Kamrup, Assam - 781128

Figure 1. Unregistered drug

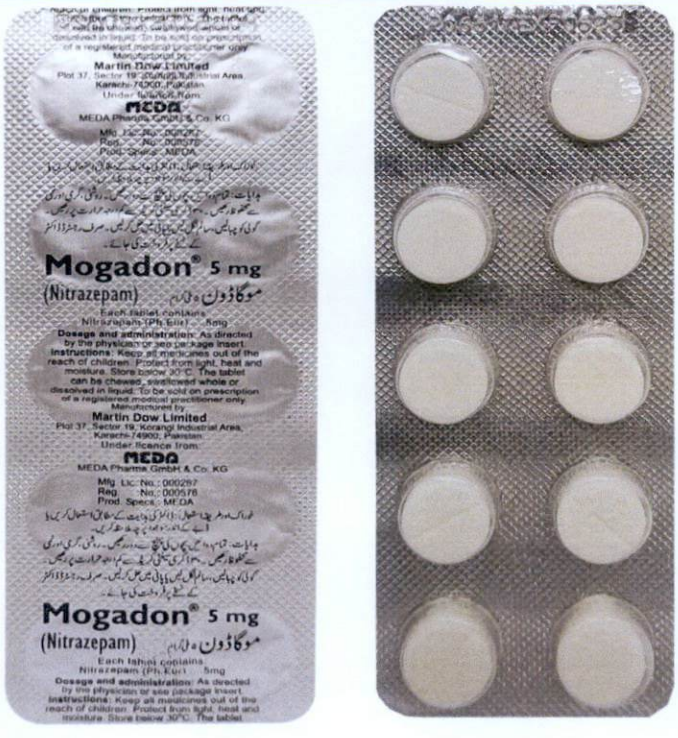


Naltrexone Tablets IP 50 mg Naltivia 50 1x10 Tablets

Manufactured by: Healing® Pharma India Pvt. Ltd. - Shop No.1, Plot no.: 25-B, Dev Industrial Estate, Gorwa, Vadodara-16. B-411, Western Edge II Premises CHS Ltd, Near Metro Mall, Western Express Highway, Borivali (East), Mumbai-400066 At. G/5 & G/6, Industrial Estate, G

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

Figure 2. Unregistered drug



Mogadon® 5 mg (Nitrazepam) Tablet

Manufactured by: Martin Dow Limited - Plot 37, Sector 19, Korangi Industrial Area, Karachi - 74900, Pakistan

Under license from: MEDA Pharma GmbH & Co. KG

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: 20220117150445