

FDA ADVISORY
No. **2024-0325**

13 FEB 2024

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. Dicyclomine Hydrochloride, Tramadol Hydrochloride & Acetaminophen Capsules Spasmo-Proxyvon® Plus 8's
2. Baidyanath Asli Ayurved Prost Aid Tablet 50's
3. Himalaya™ Bresol®-NS Saline Nasal Solution 10 ml
4. Intas Sildenafil Citrate Tablets I.P. 50 mg Intagra 50 1 x 4 tablet

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

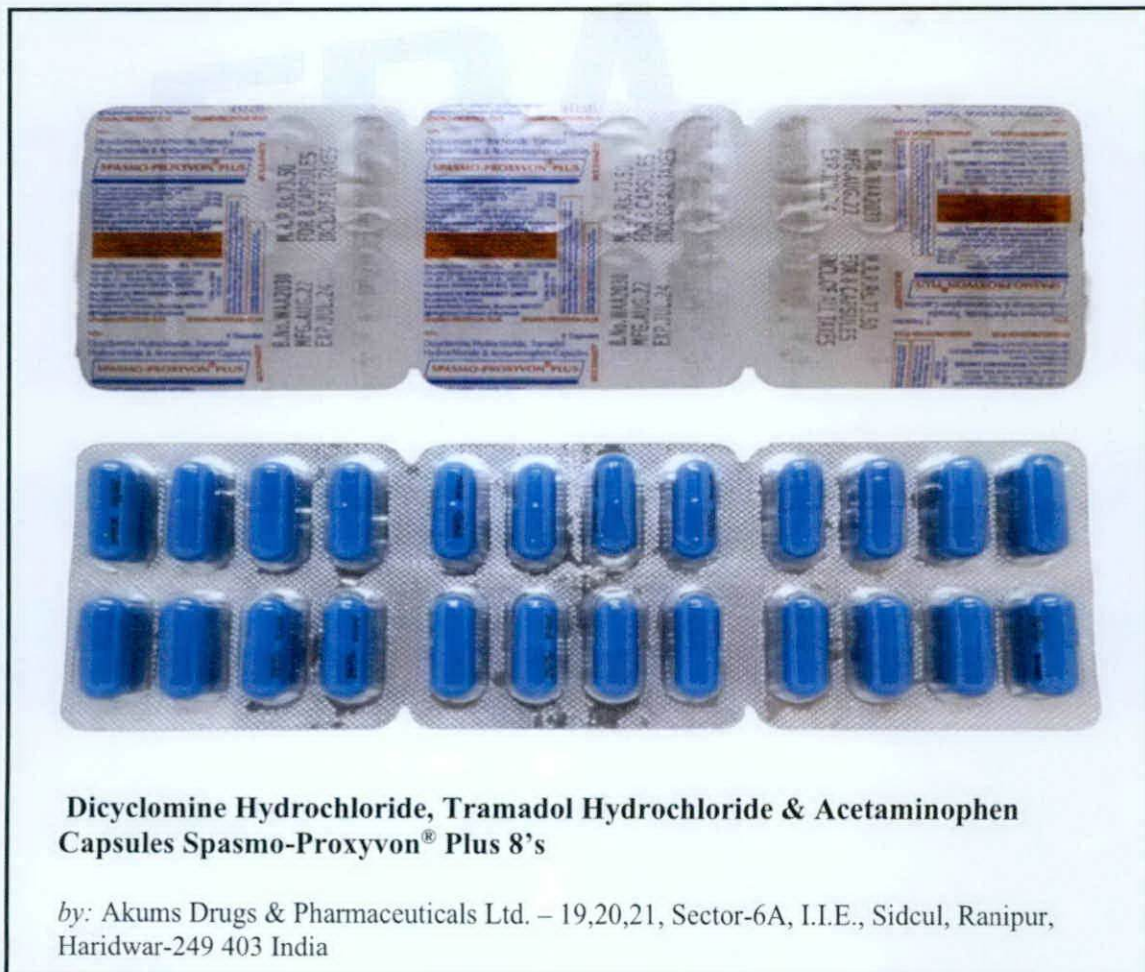


Figure 1. Unregistered drug product





Baidyanath Asli Ayurved Prost Aid Tablet 50's

by: Peethambra Ayurved Bhawan Ltd. – Sever Khera, Kashipur Disstt Udham Sing

Figure 2. Unregistered drug product



Himalaya™ Bresol®-NS Saline Nasal Solution 10 ml

by: The Himalaya Drug Company - # 9 r, Sub Layout of Plot No.9, 1st Phase, Bommasandra Industrial Area, Bengaluru 560 099

Figure 3. Unregistered drug product

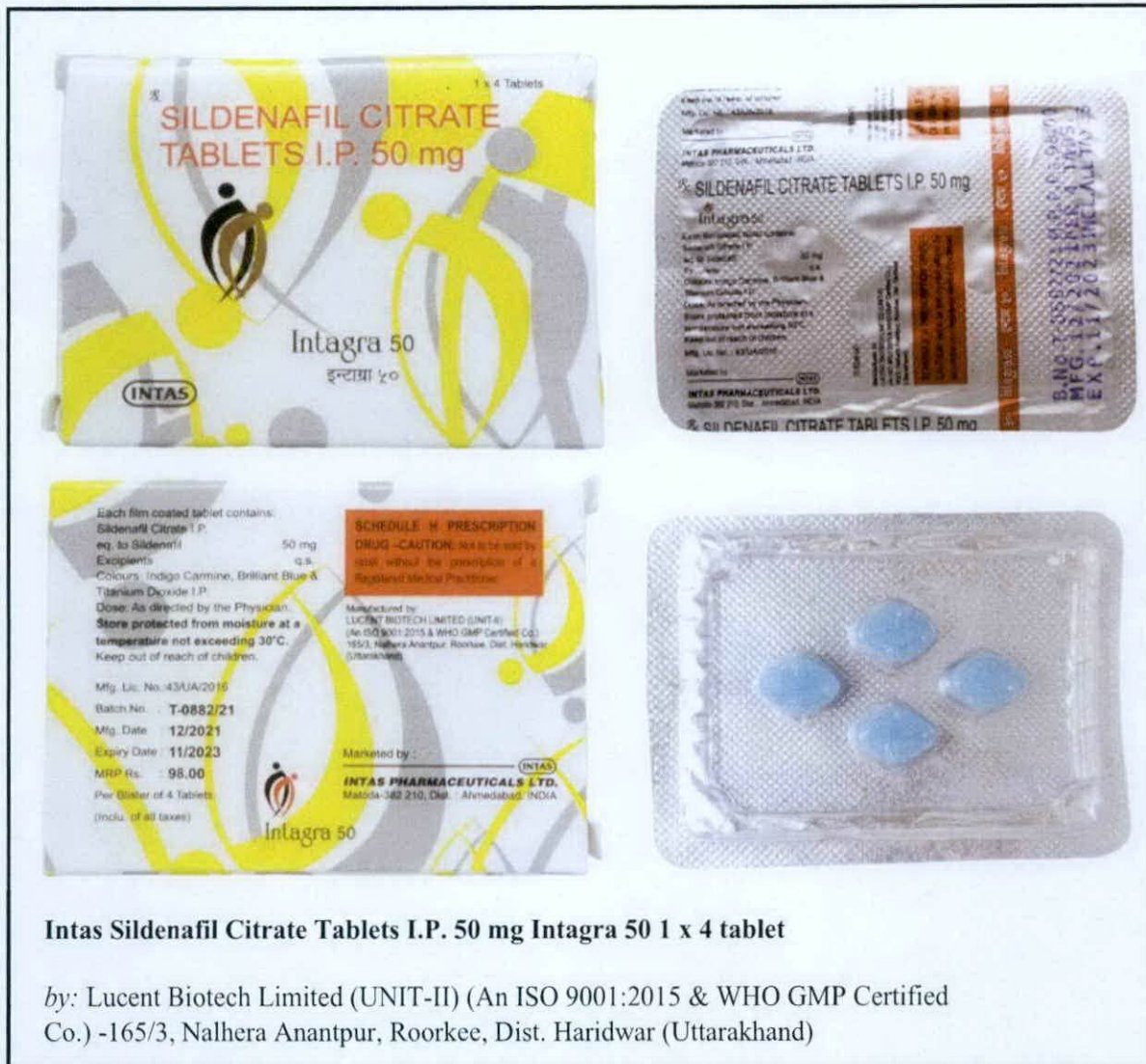


Figure 4. Unregistered drug product

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:



20240130133902


DR. SAMUEL A. ZACATE
Director General

Keywords	Dicyclomine Hydrochloride, Tramadol Hydrochloride & Acetaminophen Capsules Spasmo-Proxyvon [®] Plus 8's, Baidyanath Asli Ayurved Prost Aid Tablet 50's, Himalaya [™] Bresol [®] -NS Saline Nasal Solution 10 ml, Intas Sildenafil Citrate Tablets I.P. 50 mg Intagra 50 1 x 4 tablet, Akums Drugs & Pharmaceuticals Ltd. – 19,20,21, Sector-6A, I.I.E., Sidcul, Ranipur, Haridwar-249 403 India, Peethambra Ayurved Bhawan Ltd. – Sever Khera, Kashipur Disstt Udham Sing, The Himalaya Drug Company - # 9 r, Sub Layout of Plot No.9, 1 st Phase, Bommasandra Industrial Area, Bengaluru 560 099, Lucent Biotech Limited (UNIT-II) (An ISO 9001:2015 & WHO GMP Certified Co.) -165/3, Nalhera Anantpur, Roorkee, Dist. Haridwar (Uttarakhand)
Related issuances, laws, directives	Republic Act No. 9711 and its Implementing Rules and Regulations