



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



30 JUL 2021

FDA ADVISORY
No. **2021-1928**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. **Tobramycin & Dexamethasone (Tobracin-DM) Ophthalmic Suspension U.S.P. Eye Drops 10 mL**
2. **Ofloxacin, Dexamethasone (Omflox-DX) Ophthalmic Solution U.S.P. Eye/Ear Drops 5 mL**
3. **Ofloxacin (Omflox) Ophthalmic Solution U.S.P. Eye/Ear Drops 5 mL**
4. **Chlorbutol, Benzocaine & Paradichlorobenzene (Waxsol™) Ear Drops 10 mL**
5. **Ofloxacin, Beclomethasone Dipropionate, Clotrimazole, Lignocaine HCl (Otoquad Plus™) Ear Drops 5 mL**

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





Ofloxacin, Dexamethasone (Omflox-DX) Ophthalmic Solution U.S.P. Eye/Ear Drops 5 mL

Manufactured by: Yash Laboratories - 216/6,, Village Khundh, Taluka: Chikhli
Dist. Navsari

Marketed by: Ophthacare, Inc. Philippines /CSFP, Philippines

Figure 2. Unregistered drug product



Ofloxacin (Omflox) Ophthalmic Solution U.S. P. Eye/Ear Drops 5 mL

Manufactured by: Yash Laboratories - 216/6,, Village Khundh, Taluka: Chikhli, Dist. Navsari
Marketed by: Ophthacare, Inc. Philippines /CSFP, Philippines

Figure 3. Unregistered drug product



Figure 4. Unregistered drug product



Figure 5. 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 its 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.

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.


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