



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2021-1414**

16 JUN 2021

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. Ofloxacin, Beclomethasone, Clotrimazole Ear Drops (Otocin) 5mL
2. Moxifloxacin & Prednisolone Acetate Ophthalmic Suspension (Zoptina-P) Eye Drops 5mL
3. Dorzolamide & Timolol Maleate Eye Drops BP (Dorsun-T) 5mL
4. Mometasone Aqueous Nasal Spray BP Metospray 10mL

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

Ofloxacin, Beclomethasone, Clotrimazole Ear Drops (Otocin) 5mL
Manufacturer: Sunways (India) Pvt. Ltd. Mumbai-400 0063 At: 803/4/5, G.I.D.C, Dholka, Ahmedabad-382 225

Figure 1. Unregistered drug product



Composition :
Moxifloxacin Hydrochloride BP
Eq. to Moxifloxacin 0.5% w/v
Prednisolone Acetate USP 1.0% w/v
Benzalkonium Chloride Solution BP
Eq. to Benzalkonium Chloride 0.01% v/v
(As preservative)
Sterile Aqueous vehicle qs

DOSAGE : See Package Insert.

FOR EXTERNAL USE ONLY
NOT FOR INJECTION
SHAKE WELL BEFORE USE

WARNING:
Indiscriminate and prolonged use of this preparation may lead to glaucoma, cataract and fungal infections.

Code No. : Guj/Drugs/G/1118 A

SUNWAYS (INDIA) PVT. LTD.
Mumbai-400 063.

Moxifloxacin & Prednisolone Acetate Ophthalmic Suspension (Zoptina-P) Eye Drops 5mL

Manufacturer: Sunways (India) Pvt. Ltd. Mumbai-400 0063

Figure 2. Unregistered drug product

Composition : w/v
Dorzolamide Hydrochloride USP
Equivalent to Dorzolamide 2%
Timolol Maleate USP
Equivalent to Timolol 0.5%
Benzalkonium Chloride Solution USP
Equivalent to Benzalkonium Chloride 0.01%
(As Preservative)
Aqueous Base qs

DOSAGE :
As directed by the Physician.

KEEP IN COOL DARK PLACE
FOR EXTERNAL USE ONLY
NOT FOR INJECTION

Use the solution within one month after opening the container. If the solution becomes cloudy or dark brown it should be discarded.

Code No.: Guj./Drugs/G1118A

**MADE IN INDIA BY :
SUNWAYS (INDIA) PVT. LTD.**
Mumbai - 400 063.

Dorzolamide & Timolol Maleate Eye Drops BP (Dorsun-T) 5mL

Manufacturer: Sunways (India) Pvt. Ltd. Mumbai-400 0063

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 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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Director General

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