



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



16 JUN 2021

**FDA ADVISORY**

No. 2021-1414-A

**PARA** : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

**PAKSA** : Babala sa Publiko Tungkol sa Pagbili at Paggamit ng mga Sumusunod na Hindi Rehistradong Gamot:

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**

Pinapayuhan ng Food and Drug Administration (FDA) ang publiko laban sa pagbili at paggamit ng mga sumusunod na hindi rehistradong gamot:

**Ofloxacin,  
Beclomethasone,  
Clotrimazole  
Ear Drops**

**OTOCIN**

**COMPOSITION: w/v**

Ofloxacin	USP	0.3%
Beclomethasone Dipropionate (Anhydrous)	USP	0.025%
Clotrimazole	BP	1%
Lidocaine HCl	BP	2%
Glycerine BP and Propylene Glycol	BP	qs

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

Mfg. Lic. No. G/1128A

Made In India by:  
**SUNWAYS (INDIA) PVT. LTD.**  
Mumbai-400 063.  
At: 803/4/5, G.I.D.C, Dholka,  
Ahmedabad - 382 225.

Ofloxacin,  
Beclomethasone,  
Clotrimazole  
Ear Drops

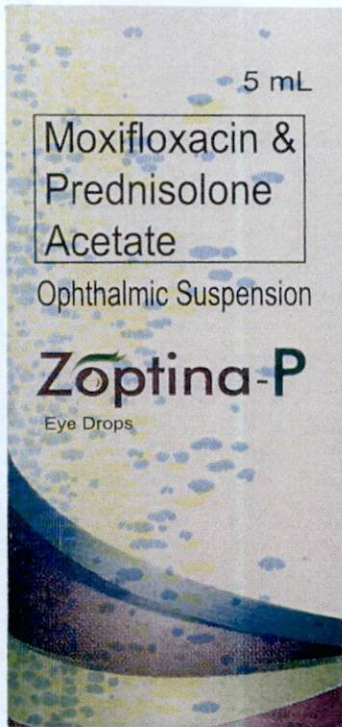
**OTOCIN**

B.N.O.HB-1901  
M.D.08/2019

**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

Larawan 1. Hindi rehistradong gamot





**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



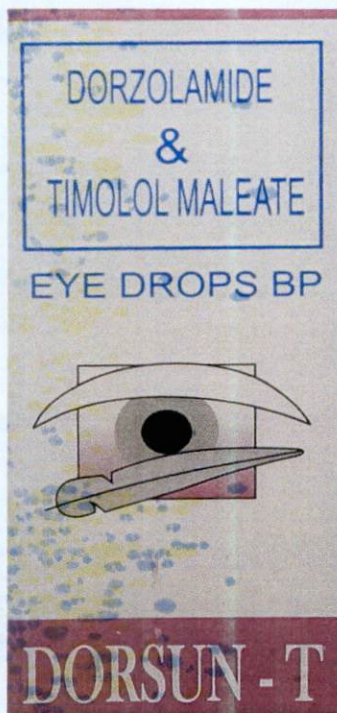
**SUNWAYS (INDIA) PVT. LTD.**  
 Mumbai-400 063.



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

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

Larawan 2. Hindi rehistradong gamot



**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/G/1118A



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

Larawan 3. Hindi rehistradong gamot

**Composition:**  
Mometasone Furoate Monohydrate eq. to Mometasone Furoate BP 0.05% w/v  
Benzalkonium Chloride Solution (as preservative) BP 0.02% v/v  
Phenylethyl alcohol (as preservative) USP 0.25% v/v  
Aqueous Buffered Vehicle qs

Each spray delivers Mometasone Furoate BP 50 mcg

**Dosage :**  
As directed by the Physician.

Store below 25°C.  
Protect from light.  
Keep away from children.

Code No. : MH/DRUGS/KD-362

Made In India for :  
**SUNWAYS (INDIA) PVT. LTD.**  
Jaiprakash Road No. 2,  
Mumbai-400 063.

**Mometasone Aqueous Nasal Spray BP Metospray 10mL**  
Manufacturer: Sunways (India) Pvt. Ltd.-Jaiprakash Road No.2, Mumbai-400 0063

Larawan 4. Hindi rehistradong gamot

Napatunayan sa pamamagitan ng isinagawang *Post-Marketing Surveillance* (PMS) ng FDA na ang mga nasabing gamot ay hindi dumaaan sa proseso ng rehistrasyon ng Ahensya at hindi nabigyan ng kaukulang awtorisasyon tulad ng *Certificate of Product Registration* (CPR). Dahil dito, hindi masisiguro ng Ahensya ang kalidad, kaligtasan at bisa nito. Samakatuwid, ang paggamit ng nasabing mga iligal na produkto ay maaaring magdulot ng panganib sa kalusugan.

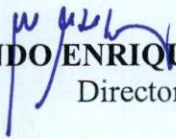
Alinsunod sa *Republic Act No. 9711*, o ang *Food and Drug Administration Act of 2009*, ang paggawa, pag-angkat, pagbenta, pamamahagi, paglipat, promosyon, pagpapatalastas o *sponsorship* ng produktong pangkalusugan nang walang kaukulang awtorisasyon mula sa FDA ay ipinagbabawal.

Ang lahat ng establisyamento at/o entidad ay binabalaang huwag mamahagi ng nasabing mga iligal na produkto hanggang sa ito ay mabigyan ng kaukulang awtorisasyon. Karampatang parusa ay mahigpit na ipatutupad sa mga lalabag.

Hinihiling sa lahat ng *Local Government Units* (LGUs) at *Law Enforcement Agencies* (LEAs) na tiyaking ang mga produktong ito ay hindi maibebenta o magagamit sa kanilang mga nasasakupan.

Para sa karagdagang impormasyon at katanungan, maaaring mag-email sa [info@fda.gov.ph](mailto:info@fda.gov.ph). Upang mag-report ng patuloy na pagtitinda o pangangalakal ng mga hindi rehistradong gamot, mag-email sa [ereport@fda.gov.ph](mailto:ereport@fda.gov.ph). Maaari ring tumawag sa *Center for Drug Regulation and Research* (CDRR) sa numerong (02) 8809-5596. Para sa mga hinihinalang hindi kanais-nais na reaksyon sa gamot, i-report agad sa FDA gamit ang link na ito: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> at kumpletuhin ang mga kinakailangang impormasyon.

Ang lahat ay hinihikayat na palaganapin ang mga nakasaad na impormasyon.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

DTN:   
20210607113324