



12 SEP 2022

FDA ADVISORY

No. 2022-1614-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. **Terramycin™ Oxytetracycline Hydrochloride with Polymyxin B Sulfate Ophthalmic Ointment 3.5 gm [Label with Foreign Character]**
2. **Canesten® Clotrimazole Cream (Clotrimazole 1% w/w) [Label with Foreign Character]**
3. **Tapazole Methimazole Tablets, USP (INN: Thiamazole) 5 mg 100 Tablets**
4. **Teva Isordil® 5 mg Sublingual Tablet Izosorbid Dinitrat 50 Tablet [Label in Foreign Language]**

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

Terramycin™
oxytetracycline hydrochloride
with polymyxin B sulfate
OPHTHALMIC OINTMENT 3.5 GM

Permit No. : HK - 02068
For External Use Only
Store below 25°C
Imported by Pfizer (Thailand) Limited, Bangkok, Thailand.
Manufactured by PT. Pfizer Indonesia, Jakarta, Indonesia.

ยาใช้ภายนอก
ยาใช้เฉพาะที่
เลขทะเบียนที่ 2C 92/49

Each gram contains oxytetracycline hydrochloride equivalent to 5 mg of oxytetracycline and 10,000 units of polymyxin B as sulfate.

DIRECTIONS: Instill into affected eye 4 to 6 times daily.

คำเตือน : ห้ามใช้ในผู้ที่มีตาแดง

Terramycin™
oxytetracycline hydrochloride
with polymyxin B sulfate.

3.5 GM


ยาใช้ภายนอก
ยาใช้เฉพาะที่
เลขทะเบียนที่ 2C 92/49

Permit No. HK - 02068
For external use only
Store below 25°C
Manufactured by Pfizer (Thailand) Limited, Bangkok, Thailand.

Terramycin™ Oxytetracycline Hydrochloride with Polymyxin B Sulfate Ophthalmic Ointment 3.5 gm [Label with Foreign Character]
Manufactured by: Pfizer (Thailand) Limited, Bangkok, Thailand

Larawan 1. Hindi rehistradong gamot





Canesten®
CLOTRIMAZOLE Cream
 (Clotrimazole 1% w/w)
 Broad Spectrum Antimycotic

Manufactured by:
 Bayer Pakistan (Pvt.) Ltd.,
 C-21, S.I.T.E., Karachi - Pakistan.
 Under licence from Bayer Consumer
 Care Ltd, Basel, Switzerland.
 Mfg: Bayer Specification
 Manufacturing Licence No. 000003
 Registration No. 003321
 GTIN(01): 08964001566366

Composition:
 Clotrimazole U.S.P. 1% w/w
 Use as prescribed by the physician.
 Do not store above 30 °C.
 Keep out of the reach of children.

FOR EXTERNAL USE ONLY
 صرف بیرونی استعمال کے لیے

10g

FOR EXTERNAL USE ONLY
 صرف بیرونی استعمال کے لیے

Canesten® Clotrimazole Cream (Clotrimazole 1% w/w) [Label with Foreign Character]
 Manufacturer: Bayer Pakistan (Pvt.) Ltd., - C-21, S.I.T.E., Karachi – Pakistan.
 Under License from Bayer Consumer Care Ltd. Basel, Switzerland.

Larawan 2. Hindi rehistradong gamot



100 TABLETS
TAPAZOLE
METHIMAZOLE
TABLETS, USP
 (INN: THIAMAZOLE)
5 mg

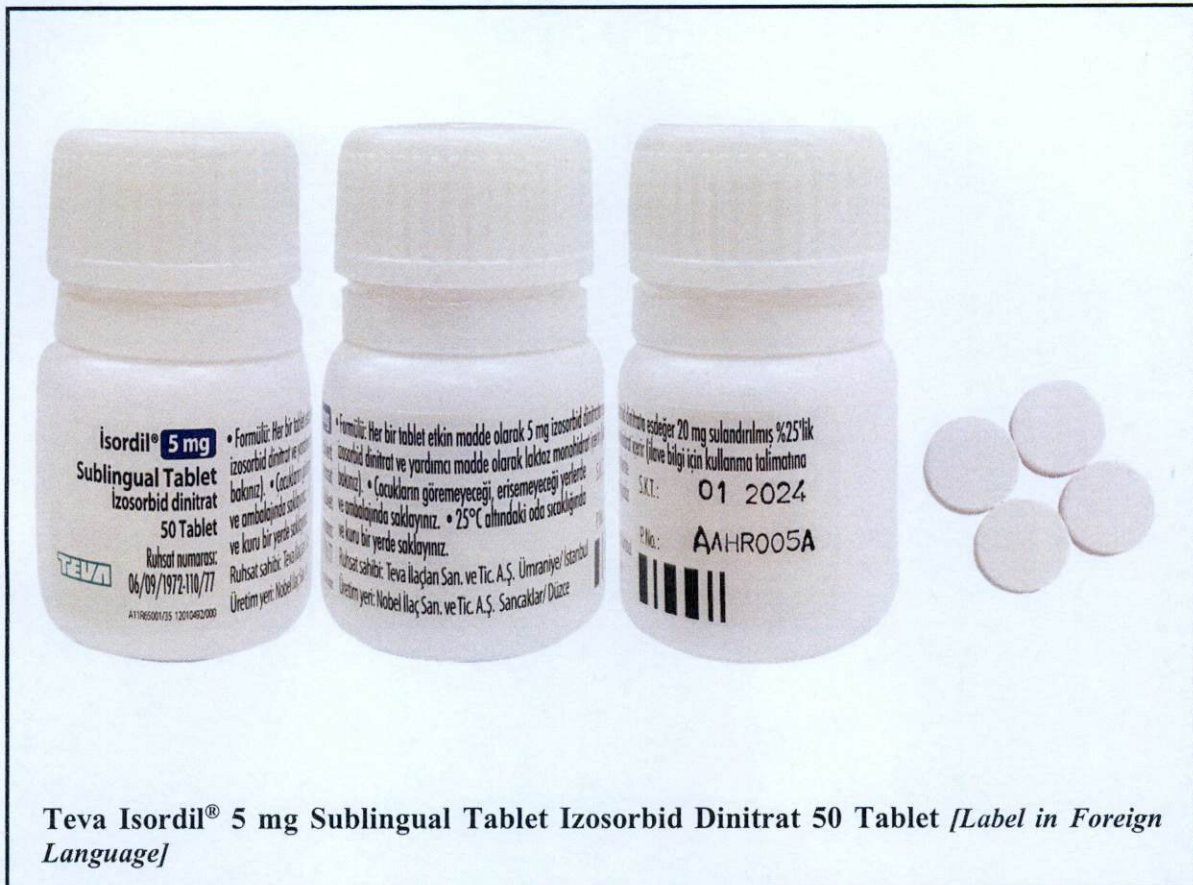
To be dispensed only by or on
 the prescription of a physician
 Manufactured by :
 OLIC (Thailand) Limited
 Ayutthaya, Thailand
 Reg. No. 1A 456/51

Batch No. 2009011
 Mfg. Date 271120
 Exp. Date 271123

ยาอันตราย
Warning - This drug may cause
toxic reactions. If such reactions
occur, discontinue the drug.
Constant supervision of the
patient is essential.
 See package insert for dosage
 information
 Dispense in a tight, light-resistant
 container.
 Keep Tightly Closed.
 Store below 30°C 991093073

Tapazole Methimazole Tablets, USP (INN: Thiamazole) 5 mg 100 Tablets
 Manufacturer: OLIC (Thailand) Limited – Ayutthaya, Thailand

Larawan 3. Hindi rehistradong gamot



Teva Isordil® 5 mg Sublingual Tablet Izosorbid Dinitrat 50 Tablet [Label in Foreign Language]

Larawan 4. Hindi rehistradong gamot

Napatunayan sa pamamagitan ng isinagawang *Post-Marketing Surveillance* (PMS) ng FDA na ang mga nasabing gamot ay hindi dumaan 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 ilegal 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 ilegal na produkto hanggang sa ito ay mabigyan ng kaukulang awtorisasyon. Karampatang parusa ay mahigpit na ipatutupad sa mga lalabag. Ugaliing tignan kung rehistrado ang produkto sa FDA sa pamamagitan ng *FDA Verification Portal feature* na makikita sa <https://verification.fda.gov.ph>.

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. Upang mag-*report* ng patuloy na pagtitinda o pangangalakal ng mga hindi rehistradong gamot, mag-*email* sa 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.

DTN:



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DR. SAMUEL A. ZACATE
Director General