



FDA ADVISORY

No. 2022-1521-A

25 AUG 2022

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. **Astellas Tacrolimus Prograf®**
2. **Aprazer Doxorubicin Hydrochloride Injection IP Lyophilized Dorucin™-50 50 mg Vial**
3. **Aprazer Docetaxel Injection IP Docecast™-80 80mg/4mL RTU Technology Injection 4 mL**

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

Astellas Tacrolimus Prograf®
Manufactured by: Astellas Ireland Co. Ltd., Kerry Plant at Killorglin, Country Kerry, Ireland
Distributor Importer: Astellas Pharma India Pvt. Ltd - 301, 3rd Floor, C & B Square, 127, Andheri-Kurla Road, Andheri (East) Mumbai - 400 069 India

Larawan 1. Hindi rehistradong gamot



PHARMACY MEDICINE
KEEP OUT OF REACH

LAZER

Rx

Doxorubicin Hydrochloride Injection IP
Lyophilized

DORUCIN™-50

50 mg Vial

Composition :
Each vial contains:
Doxorubicin Hydrochloride IP 50 mg
Excipients q.s.

FOR I.V. USE ONLY

Dissolve the lyophilized powder in 25 ml of sterile water for injection IP. Use the solution immediately after the preparation.

Storage: Store at a temperature not exceeding 30°C.

Caution : It is dangerous to take this preparation except under Medical Supervision.

SCHEDULE H PRESCRIPTION DRUG- CAUTION: Not to be sold by retail without the prescription of a Registered Medical Practitioner.

WARNING: Cytotoxic Agent: to be supplied against demand from Cancer hospitals, Institutions and against prescription of a Cancer Specialist only.

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APRAZER
Doxorubicin Hydrochloride Injection IP Lyophilized
50 mg Vial

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Doxorubicin Hydrochloride Injection IP Lyophilized
50 mg Vial

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Doxorubicin Hydrochloride Injection IP Lyophilized
50 mg Vial

Aprazer Doxorubicin Hydrochloride Injection IP Lyophilized Dorucin™-50 50 mg Vial
Manufactured by: Aprazer Healthcare Pvt. Ltd.
by: Aprazer

Larawan 2. Hindi rehistradong gamot

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

Rx

Docetaxel Injection IP

DOCEKAST™-80

80 mg/4ml
RTU TECHNOLOGY
For Intravenous Infusion Dilution
Injection 4 ml

Single Vial Formulation
Each ml contains:
Docetaxel (As Trihydrate) IP eq. to Anhydrous Docetaxel.....20 mg
Polyorbitalate 80 IP.....540 mg
Dehydrated Alcohol IP.....395 mg

DOSEAGE:
As directed by the Oncologist. Please refer accompanying package insert for detailed dosage, directions of use and precautions.

STORAGE: Store at a temperature not exceeding 25°C.

SCHEDULE H PRESCRIPTION DRUG- CAUTION: Not to be sold by retail without the prescription of a Registered Medical Practitioner.

WARNING - CYTOTOXIC AGENT: To be sold by retail on the prescription of an Oncologist, Institution & Cancer specialist only.

WARNING: This injection should not be used if it contains visible particulate matter. Do not use if cloudiness or precipitate is observed.

APRAZER
Docetaxel Injection IP
80 mg/4ml
DOCEKAST-80

APRAZER
Docetaxel Injection IP
80 mg/4ml
DOCEKAST-80

APRAZER
Docetaxel Injection IP
80 mg/4ml
DOCEKAST-80

Aprazer Docetaxel Injection IP Docekast™ -80 80mg/4mL RTU Technology Injection 4 mL
Manufactured by: Beta Drugs Ltd. – Kharuni-Lodhimajra Road, Vil. Nandpur, Baddi, Distt Solan, Himachal Pradesh-173205
Marketed by: Aprazer Healthcare Pvt., Ltd. – B-256, 2nd Floor, Naraina Phase-1, New Delhi-110028, (India)

Larawan 3. 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 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://primary-reporting.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