



FDA-2021NVT68IGQ9BMUZZNRMFO1



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City



CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act (R.A.) No. 3720 as amended, known as the Foods, Drugs, Devices and Cosmetics Act, and consistent with R.A. No. 6675, known as the Generics Act of 1988, and R.A. No. 9711, otherwise known as the Food and Drug Administration Act of 2009, the product described hereunder has been found to conform with the requirements and standards for marketing authorization of pharmaceutical products per existing regulations in force as of date hereof.

Registration Number : **DRP-6649**

Generic Name : Betahistine Hydrochloride
Brand Name : Dizzex
Dosage Strength & Form : 16 mg Tablet
Pharmacologic Category : Antivertigo
Classification : Prescription Drug (Rx)
Approved Shelf-life : 24 months
Storage Condition : Store at temperatures not exceeding 30°C.
Packaging : Alu – Alu Blister Pack x 10's (Box of 100's)

Manufacturer : Flamingo Pharmaceuticals Ltd.
R-662 T.T.C Industrial Area, MIDC, Rabale, Navi
Mumbai Thane 400701, Maharashtra State, India

Importer/ Distributor : Hexagon Pharmaceuticals
Hexagon Corporate Center, 1471 Quezon Avenue,
Brgy. West Triangle, Quezon City, Metro Manila

The marketing authorization shall be valid until **22 November 2022** subject to the conditions listed on the reverse side. No change in the formulation, labelling and commercial presentation of this product shall be made at any time during the effectivity of this registration without prior written approval of this Office.

This marketing authorization is subject to suspension, cancellation or recall should any violation of R.A. No. 3720, R.A. No. 6675 and R.A. No. 9711 and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this **12 July 2021**.

By Authority of the Director General
Per FDA Order No. 2016-005

JESUSA JOYCE N. CIRUNAY, RPh

Director IV
Center for Drug Regulation and Research

REG. STATUS : Automatic Renewal (Compliance)
AMOUNT : Php 10,100.00
OR NUMBER : 0904704
DATE : 23 October 2017
BAR CODE : 
DOC TRACK : 2 0 1 7 1 0 1 9 1 0 1 3 5 8



Management
System
ISO 9001:2015
www.tuv.com
ID 9105072306



FDA-051409

Registration Number : DRP-6649

SPECIAL CONDITION:

Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by FDA, that Registrant has the right or privilege to the use of the name or brand so registered; Registrant hereby agrees and affirms to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or intellectual property right arising from the registration of the product.

- | | | |
|-------------------------------------|----------|---|
| <input type="checkbox"/> | A | This is subject to batch notification. |
| <input type="checkbox"/> | B | This is subject to lot release certification. |
| <input type="checkbox"/> | C | This is subject to compliance with the requirements under FDA Circular No. 2013-004 for Monitored Release (MR) drug products. |
| <input checked="" type="checkbox"/> | D | Subject to post-marketing surveillance of the marketing authorization holder's strict compliance to the Generic Labeling Requirements following the applicable provisions of A.O No. 2016-0008 for drug products for human use and A.O. No. 105 s. 1991 for veterinary drug products. |
| <input type="checkbox"/> | E | Submit a satisfactory Bioequivalence Study Report or Biowaiver (whichever is applicable) within the validity of this CPR in accordance with FDA Circular No. 2016-019. |
| <input type="checkbox"/> | F | Dangerous Drug - To be prescribed by PDEA S-2 licensed practitioner in a DOH (yellow) prescription form. It is a habit-forming drug. |
| <input type="checkbox"/> | G | Dangerous Drug - To be prescribed by PDEA S-2 licensed practitioner in a personalized ordinary prescription. It is a habit-forming drug. |
| <input type="checkbox"/> | H | Patient Information Leaflet - Appropriate information for the consumers shall be written in Filipino and/or local dialects, as appropriate. |
| <input checked="" type="checkbox"/> | I | Submit a Certificate of Good Manufacturing Practice (GMP) Compliance of Foreign Drug Manufacturer(s) within the validity of this CPR in accordance with A. O. No. 2013-0022 and FDA Circular No. 2014-016. |
| <input checked="" type="checkbox"/> | J | Review of the submitted Bioequivalence Study Report or Biowaiver, whichever is applicable, shall be completed by the FDA within the validity of this CPR; correspondingly, this CPR shall be revoked if product interchangeability has not been established. |
| <input type="checkbox"/> | K | Subject to satisfactory compliance to the post-approval commitments detailed in the letter accompanying this CPR. |

REMARKS:

This Certificate of Product Registration (CPR) is granted following Department Circular 2011-0101: The Rules and Regulations Implementing Republic Act No. 9711 - The Food and Drug Administration Act of 2009.

This Certificate of Product Registration (CPR) is revalidated to reflect its full validity to 22 November 2022. This cancels CPR series number FDA-0237185 issued on 16 January 2018 valid until 22 November 2020.