FDA-2021XVW6UX51JQJXPQDQCFWD

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

FDA Food and Drug Administration PHILIPPINES

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-7807**
Generic Name	:	Hyoscine-N-Butylbromide
Brand Name	:	None
Dosage Strength & Form	:	10 mg Tablet
Pharmacologic Category	:	Anticholinergic
Classification	:	Prescription Drug (Rx)
Approved Shelf-life	:	24 months
Storage Condition	:	Store at temperatures not exceeding 30°C
Packaging	:	Alu/Clear PVC Blister Pack x 20's (Box of 100's)
Manufacturer	:	Vonwelt Inc. Brgy. Sabang, Magdalena, Laguna

The marketing authorization shall be valid until **29 October 2025** subject to the conditions listed on the reverse side. No change in the formulation, labeling 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 **18 February 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	:	**Renewal**
AMOUNT	:	**Php 7,575.00**
OR NUMBER	:	**Seq. No. 112320204892**
DATE	:	**23-Nov-2020**
BAR CODE DOC TRACK	:	2 0 2 0 1 1 0 6 1 3 3 7 5 5

TÜVRheinland CERTIFIED Management System ISO 9001:2015 www.tuv.com ID 9105073396

FDA-05088816

Registration Number : DRP-7807

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.

	A	This is subject to batch notification.
	B	This is subject to lot release certification.
	C	This is subject to compliance with the requirements under FDA Circular No. 2018-012 for Monitored Release (MR) drug products.
X	**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.
	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.
	F	Dangerous Drug - To be prescribed by a PDEA S-2 licensed practitioner in a DOH (yellow) prescription form. It is a habit-forming drug.
	G	Dangerous Drug - To be prescribed by a PDEA S-2 licensed practitioner in a personalized ordinary prescription form. It is a habit-forming drug.
	H	Patient Information Leaflet - Appropriate information for the consumers shall be written in Filipino and/or local dialects, as appropriate.
	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 2014-016.
	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.
	K	Subject to satisfactory compliance to the post-approval commitments detailed in the letter accompanying this CPR.

REMARKS:

The product has fulfilled the requirements of product interchangeability/equivalence evidence with the submission of a satisfactory Biowaiver based on Biopharmaceutics Classification System (BCS).

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.

Exhaustion of all existing inventory of the previous labeling materials is allowed only until **18 February 2022**. No further extension shall be granted.