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-4222**
Generic Name:	Methylergometrine Maleate
Brand Name:	Ergon
Dosage Strength & Form:	125 mcg Film-Coated Tablet
Pharmacologic Category:	Uterotonic (Ergot Alkaloid)
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 10's (Box of 50'S and 100's)
Manufacturer:	Jayson Pharmaceuticals Ltd. 231 Tejgaon Industrial Area, Dhaka, 1208, Bangladesh
Importer:	Aglobal Care, Inc. Unit 6, 2/F 8467 Nassons Bldg., West Service Road, South Super Highway, Parañaque City, Metro Manila
Distributor:	Aglobal Care, Inc. Unit 6, 2/F 8467 Nassons Bldg., West Service Road, South Super Highway, Parañaque City, Metro Manila

The marketing authorization shall be valid until **20 April 2027** 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 **21 April 2022**

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

Jesusa Joyce N. Cirunay, RPh

Director IV, Center for Drug Regulation and Research

This electronic-CPR (eCPR) is computer generated and does not require signature

Registration Number: **DRP-4222**

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.

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.

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.

REMARKS:

This Certificate of Product Registration (CPR) is revalidated to reflect the full validity until 20 April 2027.