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**MEDICINES CONTROL AGENCY**

Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162, Serekunda, The Gambia, Website: [www.mca.gm](http://www.mca.gm); E-mail: info@mca.gm; Tel. No.: +2204380632

**Application for Marketing authorisation (Registration) of Medicines**

[ ]  **Generic Medicine** [ ]  **New Chemical Entity (New Active Substance)**

[ ]  **Biological** [ ]  **Herbal Medicinal Product** [ ]  **Veterinary Medicine**

|  |
| --- |
| Proprietary name of the product International Non-Proprietary Name (INN):   |
| Route of Administration Dosage form / strength  |

**MANUFACTURER**

|  |
| --- |
| Name.  |
| Premises/Business Address  Tel Email Website  |

**Marketing Authorisation Holder (MAH)**

|  |
| --- |
| Name.  |
| Premises/Business Address  Tel Email Website  |

**Local Representative** (if applicable)

|  |
| --- |
| Name  |
| Address + Full Contact Details   Tel Email Website  |

**qualified Person for Pharmacovigilance (QPPV)**

|  |
| --- |
| Name  |
| Address + Full Contact Details   Tel Email Website  |

**STATUS OF APPLICANT**

|  |
| --- |
| [ ]  Manufacturer[ ]  MAH [ ]  Local Representative[ ]  Importer[ ]  Other (specify)  |

**Composition of Product:
(name and quantity of active (pharmaceutical) ingredients & excipients)**

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|  |

**INDICATIONS AND DOSAGES:**

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|  |

**PHARMACOLOGICAL CATEGORY/Pharmacotherapeutic group/ATC Code:**

|  |
| --- |
|  |

**MARKETING AUTHORISATION (MA)/REGISTRATION IN OTHER COUNTRIES (Pending or approved):**

|  |
| --- |
|  |

**PACKAGE SIZES AND PRESENTATION**

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| --- |
|  |

**Dispensing Category (**tick as applicable**):**

|  |
| --- |
| [ ]  Prescription Only Medicines (POM) [ ]  Pharmacy Only Medicine (PM) [ ]  Over The Counter Medicines (OTC) [ ]  Controlled Drug (CD) |

**MISCELLANEOUS (Special Conditions, etc.)**

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|  |

**ENCLOSURES** (tick what is applicable)

|  |
| --- |
| [ ]  CTD Dossier [ ]  Manufacturing Licence [ ]  GMP Certificate |
| [ ]  Container labels [ ]  SmPC [ ]  Package insert |
| [ ]  MA/Registration certificate(s) from country of origin and others, as applicable[ ]  Risk management plan (if applicable) |
| [ ]  Samples # [ ]  Other  |

**DECLARATION:**

I, the undersigned certify that the information in the accompanying documentation concerning the application for marketing authorisation (registration) of the medicine indicated herein is true and reflects the total information available.

I also agree that I am obliged to comply with the requirements of the Agency related to the stated product at any time in the future.

Name of Applicant:

Position/Designation and relation to MAH:

Address and Contact Details:

Signature of Applicant: Date:

**OFFICIAL USE**

|  |
| --- |
| Application no:  |
| Comments |