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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](mailto: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)**

|  |
| --- |
|  |

**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 |