MEMORANDUM DOCUMENT

THE VETERINARY MEDICINES REGULATIONS

**OFFICIAL - SENSITIVE**

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| **Marketing Authorisation No:** | **Vm** |
|  |  |
| **EU Authorisation No:** | **EU/** |
| **Product Name (in full):** |  |
|  |  |
| **Granted to:** |  |

**1. LEGAL CATEGORY[[1]](#endnote-1)**

Authorised Veterinary Medicine – General Sales List: A veterinary medicinal product classified as AVM-GSL may be supplied by any retailer as there are no restrictions on its supply.

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| **AVM - GSL** |

**1. LEGAL CATEGORY**

Non Food Animal – Veterinarian, Pharmacist or SQP: A veterinary medicinal product classified as NFA-VPS may be supplied without a prescription by a Registered Qualified Person (RQP) as follows: (i) a registered veterinary surgeon; (ii) a registered pharmacist; or (iii) a registered suitably qualified person (SQP).

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| **NFA - VPS** |

**1. LEGAL CATEGORY**

Prescription Only Medicines – Veterinarian, Pharmacist and SQP: A veterinary medicinal product classified as POM-VPS may only be supplied in accordance with a prescription from a Registered Qualified Person (RQP) as follows: (i) a registered veterinary surgeon; (ii) a registered pharmacist, or (iii) a registered suitably qualified person (SQP).

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| **POM - VPS** |

**1. LEGAL CATEGORY**

Prescription Only Medicine – Veterinarians: A veterinary medicinal product classified as POM-V may only be supplied in accordance with a prescription from a veterinary surgeon following a clinical assessment of the animal or group of animals.

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| **POM – V** |

**2. COMPOSITION PER DOSE**

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|  | **Active substance** | **Quantity (where applicable include at release and end of shelf-life)** |
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|  |  |  |
|  | **Adjuvant** |  |
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|  |  |  |
|  | Excipient |  |
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|  | **Please Note:**  The MA Memorandum summarises information contained in the product dossier. The title used for an ingredient recorded in the MA Memorandum is not necessarily that currently used in the European or other pharmacopoeia. To avoid the need to issue updated documents reflecting changes in, or additions to, the pharmacopoeia, the VMD employs its own standardised title. |

**3. PACK DETAILS (A)[[2]](#endnote-2)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | (i) | Size:[[3]](#endnote-3) |  |
|  |  |  |  |
|  | (ii) | Container: |  |
|  |  |  |  |
|  | (iii) | Closure: |  |
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**PACK DETAILS (B)**

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|  | (i) | Size: |  |
|  |  |  |  |
|  | (ii) | Container: |  |
|  |  |  |  |
|  | (iii) | Closure: |  |
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**4. MANUFACTURER(S) OF ACTIVE SUBSTANCE**

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| (i) |  |
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| (ii) |  |

**5. SITE(S) FOR BLENDING, FILLING AND ASSEMBLY**

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| (i) |  |
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| (ii) |  |

**6. SITE(S) FOR QC TESTING**

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| (i) |  |
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| (ii) |  |

**7. SITE(S) FOR LABELLING**

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| (i) |  |
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| (ii) |  |

**8. SITE(S) FOR BATCH RELEASE**

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| (i) |  |
|  |  |
| (ii) |  |

**9. INGREDIENTS OF RUMINANT ORIGIN[[4]](#endnote-4)**

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|  | **Format 1:**  Veterinary medicinal products for which starting materials are used as defined in Section 2 of the CPMP/CVMP *Note for Guidance for Minimising the Risk of* *Transmitting Animal Spongiform Encephalopathy Agents via Veterinary Medicinal Products* and for which Ph. Eur. TSE certificates are available. |

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|  | **Ingredient** | **Starting Material** | Supplier | **Certificate Number** |
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| **Seed Material** | **Species of origin** | **Risk materials used** | **Method of Demonstration of Compliance** |
|  |  |  | Scientific data |
|  |  |  | Scientific data |
|  |  |  | Scientific data |

|  |  |
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|  | In accordance with Section 2 of the CPMP/CVMP *Note for Guidance for Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via* *Human and Veterinary Medicinal Products* (EMEA/410/01). |

**9. INGREDIENTS OF RUMINANT ORIGIN**

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|  | **Format 2:**  Veterinary medicinal products for which starting materials are used as defined in Section 2 of the CPMP/CVMP *Note for Guidance for Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Veterinary Medicinal Products* (EMEA/410/01) and for which one or more of these materials no Ph. Eur. TSE certificates are available, but that scientific data demonstrating compliance with the updated TSE Note for Guidance have been submitted. |

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|  | **Ingredient** | **Starting Material** | Supplier | **Method of Demonstration of Compliance** |
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|  |  |  | Suppliers notified and approved by VMD | Scientific Data – milk suitable for human consumption |

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| **Seed Material** | **Species of origin** | **Risk materials used** | **Method of Demonstration of Compliance** |
|  |  |  | Scientific data |
|  |  |  | Scientific data |
|  |  |  | Scientific data |

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|  | In accordance with Section 2 of the CPMP/CVMP *Note for Guidance for Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products* (EMEA/410/01). |

**9. INGREDIENTS OF RUMINANT ORIGIN**

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|  | **Format 3**  No materials within scope |
|  |  |
|  | In accordance with Section 2 of the CPMP/CVMP *Note for Guidance for Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Veterinary Medicinal Products* (EMEA/410/01). |

**10. IMPORTER OF FINAL DOSAGE FORM FROM OUTSIDE THE UK (where applicable)**

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**11. SITE(S) FOR QC RETESTING IF IMPORTED FROM OUTSIDE THE UK (where applicable)**

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**12. DISTRIBUTOR[[5]](#endnote-5)**

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**13. LOCAL REPRESENTATIVE**

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1. Delete as applicable [↑](#endnote-ref-1)
2. Repeat these tables, one for each pack type [↑](#endnote-ref-2)
3. Insert the number of units, mass or volume contained in the primary pack [↑](#endnote-ref-3)
4. Complete these tables and delete as appropriate [↑](#endnote-ref-4)
5. If this is the MAH, insert 'Same as MAH'. [↑](#endnote-ref-5)