MEMORANDUM DOCUMENT

##### THE VETERINARY MEDICINES REGULATIONS

**OFFICIAL‑SENSITIVE**

|  |  |
| --- | --- |
| **Marketing Authorisation No:** | Vm  |
|  |  |
| **EU Authorisation No:** | **EU/** |
|  |  |
| **Product Name:** |  |
|  |  |
| **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**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Active substance(s)** | **Grade[[2]](#endnote-2)** | **mg/ml[[3]](#endnote-3)** |
|  |  |  |  |
|  |  |  |  |
|  | Other substance(s) |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  | Overages[[4]](#endnote-4) |  |  |
|  |  |

**3. PACK DETAILS (A)[[5]](#endnote-5)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | (i)  | Size[[6]](#endnote-6): |  |
|  |  |  |  |
|  | (ii) | Container: |  |
|  |  |  |  |
|  | (iii) | Closure: |  |
|  |  |  |  |
|  | (iv) | Dosing device: | Define or Not specified |
|  |  |  |  |
|  | (v) | Secondary pack: | Define or None specified |

 **PACK DETAILS (B)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | (i)  | Size: |  |
|  |  |  |  |
|  | (ii) | Container: |  |
|  |  |  |  |
|  | (iii) | Closure: |  |
|  |  |  |  |
|  | (iv) | Dosing device: | Define or Not specified |
|  |  |  |  |
|  | (v) | Secondary pack: | Define or None specified |

**4. MANUFACTURER(S) OF ACTIVE SUBSTANCE**

4.1 (indicating stage[s] of manufacture if necessary)

|  |  |
| --- | --- |
|  | **Active Substance 1** |
|  | Name and address of manufacturer |
|  |  |
|  | In accordance with DMF[[7]](#endnote-7) |
|  |  |
|  | In accordance with Ph. Eur. Certificate of Suitability R[X]-CEP \*\*\*\*-\*\*\*-Rev [XX] |

|  |  |
| --- | --- |
|  | **Active Substance 2** |
|  | Name and address of manufacturer |
|  |  |
|  | In accordance with DMF |
|  |  |
|  | In accordance with Ph. Eur. Certificate of Suitability R[X]-CEP \*\*\*\*-\*\*\*-Rev [XX] |

**5. INGREDIENTS OF RUMINANT ORIGIN[[8]](#endnote-8)**

|  |  |
| --- | --- |
|  | **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. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **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 |

|  |  |
| --- | --- |
|  | 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). |

**5. INGREDIENTS OF RUMINANT ORIGIN**

|  |  |
| --- | --- |
|  | **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. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **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 |

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

|  |  |
| --- | --- |
|  | 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). |

**5. INGREDIENTS OF RUMINANT ORIGIN**

|  |  |
| --- | --- |
|  | **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). |

**6. MANUFACTURER(S) OF DOSAGE FORM[[9]](#endnote-9)**

|  |  |
| --- | --- |
| (i) |  |

|  |  |
| --- | --- |
| (ii) |  |

|  |  |
| --- | --- |
|  | **Site(s) of Batch Release** |
| (i) |  |

|  |  |
| --- | --- |
|  | **Site(s) of Batch Control** |
| (i) |  |

**7. ASSEMBLER(S) OF DOSAGE FORM**

|  |  |
| --- | --- |
| (i) |  |

|  |  |
| --- | --- |
| (ii) |  |

|  |  |
| --- | --- |
|  | **Secondary Assembly Only** |
| (i) |  |

|  |  |
| --- | --- |
| (ii) |  |

**8. IMPORTER OF FINAL DOSAGE FORM FROM OUTSIDE THE UK**

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| --- | --- |
|  |  |

**9. DISTRIBUTOR[[10]](#endnote-10)**

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**10. LOCAL REPRESENTATIVE**

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1. Delete as applicable [↑](#endnote-ref-1)
2. Indicate whether the substance complies with the Ph. Eur., BP, USP, USNF, MS (manufacturer's specification or other appropriate quality standard [↑](#endnote-ref-2)
3. Replace this with appropriate units e.g mg/g, mg/tablet etc… [↑](#endnote-ref-3)
4. Either state 'None' or indicate which substances have an overage applied, its amount and whether this is to compensate for losses during manufacture or to compensate for losses on stability [↑](#endnote-ref-4)
5. Repeat these tables, one for each pack type [↑](#endnote-ref-5)
6. Insert the number of units, mass or volume contained in the primary pack [↑](#endnote-ref-6)
7. This can be the UK DMF reference, or the ASMF holder's references for the applicant's and restricted sections of the ASMF [↑](#endnote-ref-7)
8. Complete these tables and delete as appropriate [↑](#endnote-ref-8)
9. This should include any sites of processing of materials or intermediate products. For example, micronisation/sterilisation of the active substance, excipients or intermediate products [↑](#endnote-ref-9)
10. If this is the MAH, insert 'Same as MAH'. [↑](#endnote-ref-10)