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**For UK National**

**Marketing Authorisation Applications**

**NATIONAL SPC/QRD TEMPLATE**

[*SUMMARY OF PRODUCT CHARACTERISTICS - SPC 3*](#_Toc413844187)

[*THE OUTER/IMMEDIATE PACKAGE 6*](#_Toc413844188)

[*SMALL IMMEDIATE PACKAGING UNITS 8*](#_Toc413844189)

[*BLISTERS OR STRIPS 9*](#_Toc413844190)

[*IMMEDIATE DILUENT LABEL 10*](#_Toc413844191)

[*PACKAGE LEAFLET 11*](#_Toc413844192)

[*LABEL ONLY - NO PACKAGE LEAFLET, E.g. Concertina Labels. 14*](#_Toc413844193)

**Please note: This document should be used as a template for national marketing authorisation applications only. The guidance contained is national specific and can be used in addition to EU QRD template guidance available on the EMA website and implemented according to the Product Literature Standard available on www.gov.uk.**

# SUMMARY OF PRODUCT CHARACTERISTICS

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**3. PHARMACEUTICAL FORM**

**4. CLINICAL PARTICULARS**

**4.1** **Target species**

**4.2 Indications for use, specifying the target species**

**4.3 Contraindications**

**4.4 Special warnings for each target species**

**4.5 Special precautions for use**

 i) Special precautions for use in animals

 ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

 iii) Other precautions

**4.6 Adverse reactions (frequency and seriousness)**

**4.7 Use during pregnancy, lactation or lay**

**4.8 Interaction with other medicinal products and other forms of interaction**

**4.9 Amount(s) to be administered and administration route**

**4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

**4.11 Withdrawal period(s)**

**5. <PHARMACOLOGICAL> <IMMUNOLOGICAL> PROPERTIES**

**Pharmacotherapeutic group:**

**ATC Vet Code:**

**<5.1 Pharmacodynamic properties> [not applicable for immunologicals.]**

**<5.2 Pharmacokinetic particulars> [not applicable for immunologicals.]**

**<5.3 Environmental properties> [if not applicable delete this section.]**

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

**6.2 Major Incompatibilities**

**6.3 Shelf life**

**6.4 Special precautions for storage**

**6.5 Nature and composition of immediate packaging**

**6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

**7 MARKETING AUTHORISATION HOLDER**

**8. MARKETING AUTHORISATION NUMBER(S)**

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

**10. DATE OF REVISION OF THE TEXT**

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

# PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

**3. PHARMACEUTICAL FORM**

**4. PACKAGE SIZE**

**5. TARGET SPECIES**

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

<User Warnings>

**10. EXPIRY DATE**

**11. SPECIAL STORAGE CONDITIONS**

Keep the container in the outer carton.

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE** *[Distribution category]*

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| --- |
| POM-VPS |

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| --- |
| POM-V |

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| --- |
| AVM-GSL |

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| NFA-VPS |

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**16. MARKETING AUTHORISATION NUMBER(S)**

**Vm <number>**

**17. MANUFACTURER’S BATCH NUMBER**

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

**4. ROUTE(S) OF ADMINISTRATION**

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

**7. EXPIRY DATE**

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

# MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {NATURE/TYPE}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

**3. EXPIRY DATE**

**4. BATCH NUMBER**

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

# PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

**1. NAME OF THE DILUENT**

*The ‘trade’ name with a brief description or a more describing way of naming (Solvent /diluent for type of vaccine it can be used with or properties of the diluent).*

**2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

**3. ROUTES OF ADMINISTRATION**

*[According to “Standard terms” published by the Council of Europe. See also QRD reference document “Tables of non-standard abbreviations”.]*

Read the package leaflet before use.

**4. STORAGE CONDITIONS**

<Do not store above <25 °C> <30 °C>.>

<Store below <25 °C> <30 °C>.>

<Store in a refrigerator.>

<Store and transport refrigerated.>\*

<Store in a freezer.>

<Store and transport frozen.>\*\*

<Do not <refrigerate> <or> <freeze>.>

<Protect from frost.>\*\*\*

<Store in the original <container><package>.>

<Keep the {container}\*\*\*\* tightly closed.>

<Keep the {container}\*\*\*\* in the outer carton.>

<in order to protect from <light> <and> <moisture>>

<Protect from light.>

<Store in a dry place.>

<Protect from direct sunlight.>

<This veterinary medicinal product does not require any special storage conditions.>

<This veterinary medicinal product does not require any special temperature storage conditions.>

**5. BATCH NUMBER**

<Batch> <Lot> <BN> {number}

**6. EXPIRY DATE**

<EXP {month/year}>

**7. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

**[Include information under these headings as it appears in the SPC]**

# PACKAGE LEAFLET FOR:

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

**4. INDICATION(S)**

**5. CONTRAINDICATIONS**

**6. ADVERSE REACTIONS**

**7. TARGET SPECIES**

**8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

**9. ADVICE ON CORRECT ADMINISTRATION**

**10. WITHDRAWAL PERIOD(S)**

**11. SPECIAL STORAGE PRECAUTIONS**

**[Pharmaceuticals ONLY** *- The following statement should be included if there is an in-use shelf life (example: solution for injection)]*

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

**12. SPECIAL WARNING(S)**

<User Warnings>

For Animal Treatment Only

**[Immunologicals ONLY** - *For injectables containing mineral oil, the following statement should be included:]*

<To the user:

This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.>

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

*[It is recommended that the following reference to the VMD Website is included:]*

<Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.>

**<15. OTHER INFORMATION>**

 [Distribution category]

*Vm <number>*

# MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package leaflet {NATURE/TYPE}

*[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website. This template should only be used when all printed information is directly visible on the immediate container and cannot be used if a fold-out or concertina format is proposed.]*

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS**

**4. PHARMACEUTICAL FORM**

**5. PACKAGE SIZE**

**6. INDICATION(S)**

**7. CONTRAINDICATIONS**

**8. ADVERSE REACTIONS**

**9. TARGET SPECIES**

**10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

**11. ADVICE ON CORRECT ADMINISTRATION**

**12. WITHDRAWAL PERIOD**

**13. SPECIAL STORAGE PRECAUTIONS**

Keep the container in the outer carton.

**[Pharmaceuticals ONLY** *- The following statement should be included if there is an in-use shelf life (example: solution for injection)]*

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

**14. SPECIAL WARNING(S)**<User Warnings>

**15. EXPIRY DATE**

**16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

**17. DATE ON WHICH THE LABEL WAS LAST APPROVED**

*[It is mandatory for Exceptional Marketing Authorisations and recommended for others that the following reference to the VMD Website is included:]*

<Find more product information by searching for the Product Information Database ‘PID’ on www.gov.uk.>

**18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

*[Distribution category]*

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| POM-VPS |

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| POM-V |

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| --- |
| AVM-GSL |

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| --- |
| NFA-VPS |

**19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

**20. MARKETING AUTHORISATION NUMBER(S)**

**Vm <number>**

**21. MANUFACTURER’S BATCH NUMBER**

**<22. OTHER INFORMATION>**