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**Marketing Authorisation Applications**

**NATIONAL SPC/QRD TEMPLATE GUIDANCE**

**V1 – updated 16/06/22**

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**Please note: This document should be used as a template for national marketing authorisation applications validated on or after 28 January 2022. Further guidance, supporting the requirements contained in this template, is available on** [**www.gov.uk**](http://www.gov.uk)**. These requirements should be implemented according to the** [**Product Literature Standard.**](https://www.gov.uk/guidance/product-literature-standard-pls-for-veterinary-medicinal-products)

# 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**

Special precautions for use in animals

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

Special precautions for the protection of the environment

 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**

**<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**

**11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

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

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

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

**3. PACKAGE SIZE**

**4. TARGET SPECIES**

**5. INDICATION(S)**

**6. ROUTES OF ADMINISTRATION**

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

**9. SPECIAL STORAGE PRECAUTIONS**

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

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

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

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

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

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

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

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

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

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

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

**3. TARGET SPECIES**

**4. ROUTES OF ADMINISTRATION**

**5. WITHDRAWAL PERIODS**

**6. EXPIRY DATE**

**7. SPECIAL STORAGE PRECAUTIONS**

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

**9. BATCH NUMBER**

**10. PACKAGE SIZE**

**11. INDICATION(S)**

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

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

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

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

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

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

**2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)**

**3. BATCH NUMBER**

**4. EXPIRY DATE**

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

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

**7. WITHDRAWAL PERIOD**

**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. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)**

**3. BATCH NUMBER**

**4. EXPIRY DATE**

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

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

# PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT/SOLVENT LABEL

 **1. NAME OF THE DILUENT/SOLVENT**

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

**3. ROUTES OF ADMINISTRATION**

**4. STORAGE CONDITIONS**

**5. BATCH NUMBER**

**6. EXPIRY DATE**

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

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

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

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

**2. COMPOSITION**

**3. TARGET SPECIES**

**4. INDICATIONS FOR USE**

**5. CONTRAINDICATIONS**

**6. SPECIAL WARNING(S)**

**7. ADVERSE EVENTS**

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

**9. ADVICE ON CORRECT ADMINISTRATION**

**10. WITHDRAWAL PERIOD(S)**

**11. SPECIAL STORAGE PRECAUTIONS**

**12. SPECIAL PRECAUTIONS FOR DISPOSAL**

**13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

**14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

**15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED**

**16. CONTACT DETAILS**

**17. OTHER INFORMATION**

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

*[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 OF THE VETERINARY MEDICINAL PRODUCT**

**2. COMPOSITION**

**3. PACKAGE SIZE**

**4. TARGET SPECIES**

**5. INDICATIONS FOR USE**

**6. CONTRAINDICATIONS**

**7. SPECIAL WARNINGS**

**8. ADVERSE REACTIONS**

**9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION**

**10. ADVICE ON CORRECT ADMINISTRATION**

**11. WITHDRAWAL PERIODS**

**12. SPECIAL STORAGE PRECAUTIONS**

**13. SPECIAL PRECAUTIONS FOR DISPOSAL**

**14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

**15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

**16. DATE ON WHICH THE LABEL WAS LAST REVISED**

**17. CONTACT DETAILS**

**18. OTHER INFORMATION**

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

**20. EXPIRY DATE**

**21. BATCH NUMBER**

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