*[Version 9.1,11/2024]*

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

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

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>}

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**Active substances:**

**<Adjuvants:>**

**<Excipients:>**

|  |  |
| --- | --- |
| **<Qualitative** **composition of excipients and other constituents***>* | **<Quantitative** **composition** **if that information is essential** **for proper administration of the veterinary medicinal produc**t**>** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**3. CLINICAL INFORMATION**

**3.1 Target species**

**3.2 Indications for use for each target species**

<Onset of immunity: {x weeks}>

<Duration of immunity: {x years} {has not been established}>

**3.3 Contraindications**

<None.>

<Do not use in….>

<Do not use in cases of hypersensitivity to the active substance(s) <, to the adjuvant(s)> or to any of the excipient(s).>

**3.4 Special warnings**

<None.>

<Vaccinate healthy animals only.>

**3.5 Special precautions for use**

Special precautions for safe use in the target species:

<Not applicable.>

<Vaccinated {species} may excrete the vaccine strain up to {x <days> <weeks>} following vaccination. During this time, the contact of immunosuppressed and unvaccinated {species} with vaccinated {species} should be avoided.>

<The vaccine strain can spread to {species}. Special precautions should be taken to avoid spreading of the vaccine strain to {species}.>

<Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.>

<{Species} and unvaccinated {species} in contact with vaccinated {species} may react to the vaccine strain, presenting clinical signs such as….>

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

<Not applicable.>

<In case of accidental <self-administration> <self-injection> <ingestion> <spillage onto skin>, seek medical advice immediately and show the package leaflet or the label to the physician.>

<People with known hypersensitivity to {INN} should <avoid contact with the veterinary medicinal product.> <administer the veterinary medicinal product with caution.>>

<Personal protective equipment consisting of {specify} should be worn when handling the veterinary medicinal product.>

<The veterinary medicinal product should not be administered by pregnant women.>

<The <vaccine> <immunological veterinary medicinal product> can be pathogenic for humans. Since this <vaccine> <immunological veterinary medicinal product> has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process.>

<Vaccinated {species} may excrete the vaccine strain up to {x <days> <weeks>} following vaccination.>

<Immunocompromised persons are advised to avoid contact with the <vaccine> <immunological veterinary medicinal product> and vaccinated animals during {period}.>

<The vaccine strain can be found in the environment for up to {x <days> <weeks>}. Personnel involved in attending vaccinated {species} should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated {species}.>

<To the user:

This veterinary medicinal 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 veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal 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.>

Special precautions for the protection of the environment:

<Not applicable.>

<Other precautions:>

**3.6 Adverse events**

{Target species:}

|  |  |
| --- | --- |
| Very common  (>1 animal / 10 animals treated): | {adverse event/VeDDRA LLT (relevant additional information, adverse event/VeDDRA LLT (relevant additional information) etc.} |
| Common  (1 to 10 animals / 100 animals treated): | {adverse event/VeDDRA LLT (relevant additional information), adverse event/VeDDRA LLT (relevant additional information) etc.} |
| Uncommon  (1 to 10 animals / 1 000 animals treated): | {adverse event/VeDDRA LLT (relevant additional information), adverse event/VeDDRA LLT (relevant additional information) etc.} |
| Rare  (1 to 10 animals / 10 000 animals treated): | {adverse event/VeDDRA LLT (relevant additional information), adverse event/VeDDRA LLT (relevant additional information) etc.} |
| Very rare  (<1 animal / 10 000 animals treated, including isolated reports): | {adverse event/VeDDRA LLT (relevant additional information), adverse event/VeDDRA LLT (relevant additional information) etc.} |

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the <package leaflet> <immediate packaging> for respective contact details.

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

<The safety of the veterinary medicinal product has not been established during <pregnancy> <lactation> <lay>.>

<Pregnancy:> <and lactation:>

<Can be used during pregnancy.>

<The use is not recommended (during the whole or part of the pregnancy).>

<Do not use (during the whole or part of the pregnancy).>

<The use is not recommended during <pregnancy> <lactation>.>

<Use only according to the benefit-risk assessment by the responsible veterinarian.>

<Laboratory studies in {species} have not produced any evidence of <teratogenic>, <foetotoxic>, <maternotoxic> effects.>

<Laboratory studies in {species} have shown evidence of <teratogenic>, <foetotoxic>, <maternotoxic> effects.>

<Lactation:>

<Not applicable.>

<Laying birds:>

<Do not use in <birds in lay> <breeding birds> <and within 4 weeks before the start of the laying period>.>

<Fertility:>

<Do not use in breeding animals.>

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

<None known.>

<No data available.>

<No information is available on the safety and efficacy of this <vaccine> <immunological veterinary medicinal product> when used with any other veterinary medicinal product. A decision to use this <vaccine> <immunological veterinary medicinal product> before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.>

<Safety> <and> <efficacy> data are available which demonstrate that this <vaccine> <immunological veterinary medicinal product> can be administered on the same day but not mixed with {description of tested product(s).}>

<The <veterinary medicinal products> <vaccines> <immunological veterinary medicinal products> should be given at different sites.>

<Safety> <and> <efficacy> data are available which demonstrate that this <vaccine> <immunological veterinary medicinal product> can be administered at least {X} <days> <weeks> <before> <after> the administration of {description of tested product(s)}.>

<No information is available on the safety and efficacy of this <vaccine> <immunological veterinary medicinal product> when used with any other veterinary medicinal product except the products mentioned above. A decision to use this <vaccine> <immunological veterinary medicinal product> before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.>

<Safety> <and> <efficacy> data are available which demonstrate that this <vaccine> <immunological veterinary medicinal product> can be mixed and administered with {description of tested product(s)}.>

**3.9 Administration routes and dosage**

<The <vaccine> <immunological veterinary medicinal product> <veterinary medicinal product> should not be used if {description of the visible signs of deterioration}.>

<To ensure a correct dosage, body weight should be determined as accurately as possible.>

<The intake of medicated <feed> <water> depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of {active substance} may need to be adjusted accordingly.>

<The use of suitably calibrated measuring equipment is recommended.>

<Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:>

<The veterinary medicinal product is to be administered only for the treatment of individually fed animals or a small group of animals where the intake by individual animals can be effectively controlled.>

**3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

**3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

<Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State’s competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.>

<This veterinary medicinal product is intended to be used for the preparation of medicated feed.>

<For administration only by a veterinarian.>

<Official control authority batch release may be required for this product according to national requirements.>

<Not applicable.>

**3.12 Withdrawal periods**

<Not applicable.>

<Zero days.>

<<Meat and offal> <Eggs> <Milk> <Honey>: {X} <days> <hours>.>

<{X} degree days.>

<Not authorised for use in animals producing milk for human consumption.>

<Do not use in pregnant animals which are intended to produce milk for human consumption within {X} months of expected parturition.>

<Do not use within {X} weeks before the start of the laying period.>

<Not for use in birds producing or intended to produce eggs for human consumption.>

**4. <PHARMACOLOGICAL> <IMMUNOLOGICAL> INFORMATION**

**4.1 ATCvet code :**

{lowest available level (e.g. subgroup for chemical substance)}

**<4.2 Pharmacodynamics>**

**<4.3 Pharmacokinetics>**

**<Environmental properties>**

**5. PHARMACEUTICAL PARTICULARS**

**5.1 Major incompatibilities**

<Data> <and> <information> are available which show that this veterinary medicinal product <can> <cannot> be used simultaneously and/or dissolved in <drinking water> <or> <liquid feed> with {description of tested biocidal product(s), feed additive(s) or other substance(s) used in drinking water.}>

<This veterinary medicinal product must not be administered using drinking water containing {name of biocidal active substance 1, e.g., chlorine} as the active substance {name of active substance} degrades in the presence of <this biocidal active substance > <these biocidal active substances >.>

<This veterinary medicinal product may be administered using drinking water containing {name of biocidal active substance 1, e.g., active chlorine} at a maximum concentration of {XX} ppm.>

<No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into <drinking water> <or> <liquid feed> containing <biocidal products>, <feed additives> <or> <other substances used in drinking water.>

<Not applicable.>

<In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.>

<Do not mix with any other veterinary medicinal product <, except <solvent or other component>> <recommended> <supplied> <for use with the veterinary medicinal product> <and except those mentioned in section 3.8 above>.>

<None known.>

**5.2 Shelf life**

<Shelf life of the veterinary medicinal product as packaged for sale:>

<Shelf life after first opening the immediate packaging:>

<Shelf life after <dissolution> <dilution> <reconstitution> according to directions:>

<Shelf life after <incorporation> <mixing> into meal or pelleted feed:>

<6 months.> <…> <1 year.> <18 months.> <2 years.> <30 months.> <3 years.> <use immediately.>

**5.3 Special precautions for storage**

<Do not store above <25 °C> <30 °C>.>

<Store below <25 °C> <30 °C>.>

<Store in a refrigerator (2 °C – 8 °C).>

<Store and transport refrigerated (2 °C – 8 °C).>\*

<Store in a freezer {temperature range}.>

<Store and transport frozen {temperature range}.>\*\*

<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.>\*\*\*\*\*

*[\* The stability data generated at 25 °C/60 % RH (acc) should be taken into account when deciding whether or not transport under refrigeration is necessary. The statement should only be used in exceptional cases.*

*\*\* This statement should be used only when critical.*

*\*\*\* E.g. for containers to be stored on a farm.*

*\*\*\*\* The actual name of the container should be used (e.g. bottle, blister, etc.).*

*\*\*\*\*\* Depending on the pharmaceutical form and the properties of the product, there may be a risk of deterioration due to physical changes if subjected to low temperatures. Low temperatures may also have an effect on the packaging in certain cases. An additional statement may be necessary to take account of this possibility.]*

**5.4 Nature and composition of immediate packaging**

<Not all pack sizes may be marketed.>

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

Medicines should not be disposed of via wastewater <or household waste>.

<The veterinary medicinal product should not enter water courses as {INN/active substance(s)} may be dangerous for fish and other aquatic organisms.>

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

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

{Name}

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

**8. DATE OF FIRST AUTHORISATION**

<Date of first authorisation:> <{DD/MM/YYYY}> <{DD month YYYY}.>

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

<**LIMITED MARKETS:**>

<Marketing authorisation granted for a limited market and therefore assessment based on customised requirements for documentation. Only a limited assessment of safety or efficacy has been conducted due to the lack of comprehensive safety or efficacy data.>

<**EXCEPTIONAL CIRCUMSTANCES:**>

<Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation. Only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.>

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

<Veterinary medicinal product subject to prescription.>

<Veterinary medicinal product not subject to prescription.>

<Veterinary medicinal product subject to prescription except for some pack sizes.>

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

**ANNEX II**

*[Not applicable for MRP/DCP/SRP and national procedures]*

**OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

<None.>

**OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

**<SPECIFIC PHARMACOVIGILANCE REQUIREMENTS:>**

<The MAH shall record in the pharmacovigilance database all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance, according to the following frequency: <annually.> <every X months for the first XX years after authorisation, then annually.>>

**<SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION IN EXCEPTIONAL CIRCUMSTANCES>**

<This being an approval in exceptional circumstances and pursuant to Article 25 of Regulation (EU) 2019/6, the MAH shall conduct, within the stated timeframe, the following measures:

| **Description** | **Due date** |
| --- | --- |
|  |  |
|  |  |

>

**<OBLIGATION TO CONDUCT POST-AUTHORISATION MEASURES>**

<The MAH shall complete, within the stated timeframe, the following measures:

|  |  |
| --- | --- |
| **Description** | **Due date** |
|  |  |
|  |  |
|  |  |

>

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

**A. LABELLING**

|  |
| --- |
| **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  **{NATURE/TYPE}** |

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

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form}

|  |
| --- |
| **2. STATEMENT OF ACTIVE SUBSTANCES** |

|  |
| --- |
| **3. PACKAGE SIZE** |

|  |
| --- |
| **4. TARGET SPECIES** |

|  |
| --- |
| **5. INDICATIONS** |

|  |
| --- |
| **6. ROUTES OF ADMINISTRATION** |

|  |
| --- |
| **7. WITHDRAWAL PERIODS** |

<Withdrawal periods:>

|  |
| --- |
| **8. EXPIRY DATE** |

Exp. {mm/yyyy}

<Once <broached> <opened> <diluted> <reconstituted> <use by…> <use within…> <use immediately>.>

|  |
| --- |
| **9. SPECIAL STORAGE PRECAUTIONS** |

<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.>

*[\* The stability data generated at 25 °C/60 % RH (acc) should be taken into account when deciding whether or not transport under refrigeration is necessary. The statement should only be used in exceptional cases.*

*\*\* This statement should be used only when critical.*

*\*\*\* E.g. for containers to be stored on a farm.*

*\*\*\*\* The actual name of the container should be used (e.g. bottle, blister, etc.)].*

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

Read the package leaflet before use.

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

For animal treatment only.

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

Keep out of the sight and reach of children.

|  |
| --- |
| **13. NAME OF THE MARKETING AUTHORISATION HOLDER** |

{Name or company name or logo name of the marketing authorisation holder}

|  |
| --- |
| **14. MARKETING AUTHORISATION NUMBERS** |

EU/0/00/000/000

|  |
| --- |
| **15. BATCH NUMBER** |

Lot {number}

|  |
| --- |
| **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**  **{NATURE/TYPE}** |

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

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form}

|  |
| --- |
| **2. STATEMENT OF ACTIVE SUBSTANCES** |

|  |
| --- |
| **3. TARGET SPECIES** |

|  |
| --- |
| **4. ROUTES OF ADMINISTRATION** |

Read the package leaflet before use.

|  |
| --- |
| **5. WITHDRAWAL PERIODS** |

<Withdrawal periods:>

|  |
| --- |
| **6. EXPIRY DATE** |

Exp. {mm/yyyy}

<Once <broached> <opened> <diluted> <reconstituted> <use by…> <use within…> <use immediately.>>

|  |
| --- |
| **7. SPECIAL STORAGE PRECAUTIONS** |

<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.>

*[\* The stability data generated at 25°C/60 % RH (acc) should be taken into account when deciding whether or not transport under refrigeration is necessary. The statement should only be used in exceptional cases.*

*\*\* This statement should be used only when critical.*

*\*\*\* E.g. for containers to be stored on a farm.*

*\*\*\*\* The actual name of the container should be used (e.g. bottle, blister, etc.)].*

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

{Name or company name or logo name of the marketing authorisation holder}

|  |
| --- |
| **9. BATCH NUMBER** |

Lot {number}

|  |
| --- |
| **MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  **{NATURE/TYPE}** |

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

{(Invented) name of veterinary medicinal product}

|  |
| --- |
| **2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES** |

|  |
| --- |
| **3. BATCH NUMBER** |

Lot {number}

|  |
| --- |
| **4. EXPIRY DATE** |

Exp. {mm/yyyy}

<Once <broached> <opened> <diluted> <reconstituted> <use by…> <use within…> <use immediately>.>

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>}

**2. Composition**

**3. Target species**

**4. Indications for use**

**5. Contraindications**

**6. Special warnings**

<None.>

<Special warnings:>

<Special precautions for safe use in the target species:>

<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:>

<Pregnancy:>

<Lactation:>

<Pregnancy and lactation:>

<Laying birds:>

<Fertility:>

<Interaction with other medicinal products and other forms of interaction:>

<Overdose:>

<Special restrictions for use and special conditions for use:>

<Major incompatibilities:>

**7. Adverse events**

{Target species:}

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}*[listed in* [*Appendix I*](https://www.ema.europa.eu/documents/template-form/qrd-appendix-i-adverse-event-phv-mss-reporting-details_en.docx)*\*]*.

*[\*For the printed material, please refer to the guidance of the annotated QRD template.]*

**8. Dosage for each species, routes and method of administration**

**9. Advice on correct administration**

<Do not use {(Invented) name of veterinary medicinal product} if you notice {description of visible signs of deterioration}.>

**10. Withdrawal periods**

**11. Special storage precautions**

Keep out of the sight and reach of children.

<Do not store above <25 °C> <30 °C>.>

<Store below <25 °C> <30 °C>.>

<Store in a refrigerator (2 °C – 8 °C).>

<Store and transport refrigerated (2 °C – 8 °C).>\*

<Store in a freezer {temperature range}.>

<Store and transport frozen {temperature range}.>\*\*

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

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

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

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

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

<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.>\*\*\*\*\*

*[\* The stability data generated at 25 °C/60 % RH (acc) should be taken into account when deciding whether or not transport under refrigeration is necessary. The statement should only be used in exceptional cases.*

*\*\* This statement should be used only when critical.*

*\*\*\* E.g. for containers to be stored on a farm.*

*\*\*\*\* The actual name of the container should be used (e.g. bottle, blister, etc.).*

*\*\*\*\*\* Depending on the pharmaceutical form and the properties of the product, there may be a risk of deterioration due to physical changes if subjected to low temperatures. Low temperatures may also have an effect on the packaging in certain cases. An additional statement may be necessary to take account of this possibility.]*

Do not use this veterinary medicinal product after the expiry date which is stated on the <label> <carton> <bottle> <...> <after Exp>. <The expiry date refers to the last day of that month.>

<Shelf life after first opening the immediate packaging:….>

<Shelf life after <dissolution> <dilution> <reconstitution> according to directions:….>

<Shelf life after <incorporation> <mixing> into meal or pelleted feed:….>

**12. Special precautions for disposal**

Medicines should not be disposed of via wastewater <or household waste>.

<This veterinary medicinal product should not enter water courses as {INN/active substance(s)} may be dangerous for fish and other aquatic organisms.>

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

<Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.>

**13. Classification of veterinary medicinal products**

**14. Marketing authorisation numbers and pack sizes**

<Not all pack sizes may be marketed.>

**15. Date on which the package leaflet was last revised**

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

**16. Contact details**

Marketing authorisation holder <,> <and> <manufacturer responsible for batch release> <and contact details to report suspected adverse events>:

Manufacturer responsible for batch release:

<Local representatives <and contact details to report suspected adverse events>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

|  |  |
| --- | --- |
| **België/Belgique/Belgien**  {Nom/Naam/Name}  {Adresse/Adres/Anschrift }  BE-0000 {Localité/Stad/Stadt}  Tél/Tel: + {N° de téléphone/Telefoonnummer/  Telefonnummer}  <{E-mail}> | **Lietuva**  {pavadinimas}  {adresas}  LT {pašto indeksas} {miestas}  Tel: + {telefono numeris}  <{E-mail}> |
| **Република България**  {Наименование}  {Адрес}  BG {Град} {Пощенски код}  Teл: + {Телефонен номер}  <{E-mail}> | **Luxembourg/Luxemburg**  {Nom}  {Adresse}  L-0000 {Localité/Stadt}  Tél/Tel: + {N° de téléphone/Telefonnummer}  <{E-mail}> |
| **Česká republika**  {Název}  {Adresa}  CZ {město}  Tel: +{telefonní číslo}  <{E-mail}> | **Magyarország**  {Név}  {Cím}  HU-0000 {Város}  Tel.: + {Telefonszám}  <{E-mail}> |
| **Danmark**  {Navn}  {Adresse}  DK-0000 {by}  Tlf.: + {Telefonnummer}  <{E-mail}> | **Malta**  {Isem}  {Indirizz}  MT-0000 {Belt/Raħal}  Tel: + {Numru tat-telefon}  <{E-mail}> |
| **Deutschland**  {Name}  {Anschrift}  DE-00000 {Stadt}  Tel: + {Telefonnummer}  <{E-mail}> | **Nederland**  {Naam}  {Adres}  NL-0000 XX {stad}  Tel: + {Telefoonnummer}  <{E-mail}> |
| **Eesti**  (Nimi)  (Aadress)  EE - (Postiindeks) (Linn)  Tel: +(Telefoninumber)  <{E-mail}> | **Norge**  {Navn}  {Adresse}  N-0000 {poststed}  Tlf: + {Telefonnummer}  <{E-mail}> |
| **Ελλάδα**  {Όνομα}  {Διεύθυνση}  EL-000 00 {πόλη}  Τηλ: + {Αριθμός τηλεφώνου}  <{E-mail}> | **Österreich**  {Name}  {Anschrift}  A-00000 {Stadt}  Tel: + {Telefonnummer}  <{E-mail}> |
| **España**  {Nombre}  {Dirección}  ES-00000 {Ciudad}  Tel: + {Teléfono}  <{E-mail}> | **Polska**  {Nazwa/ Nazwisko:}  {Adres:}  PL – 00 000{Miasto:}  Tel.: + {Numer telefonu:}  <{E-mail}> |
| **France**  {Nom}  {Adresse}  FR-00000 {Localité}  Tél: + {Numéro de téléphone}  <{E-mail}> | **Portugal**  {Nome}  {Morada}  PT-0000−000 {Cidade}  Tel: + {Número de telefone}  <{E-mail}> |
| **Hrvatska**  {Ime}  {Adresa}  {Poštanski broj} {grad}  Tel: + {Telefonski broj}  <{e-mail}> | **România**  {Nume}  {Adresă}  {Oraş} {Cod poştal} – RO  Tel: + {Număr de telefon}  <{E-mail}> |
| **Ireland**  {Name}  {Address}  {Town} {Postal code} - IE  Tel: + {Telephone number}  <{E-mail}> | **Slovenija**  {Ime}  {Naslov}  SI-0000 {Mesto}  Tel: + {telefonska številka}  <{E-mail}> |
| **Ísland**  {Nafn}  {Heimilisfang}  IS-000 {Borg/Bær}  Sími: + {Símanúmer}  <{Netfang}> | **Slovenská republika**  {Meno}  {Adresa}  SK-000 00 {Mesto}  Tel: + {Telefónne číslo}  <{E-mail}> |
| **Italia**  {Nome}  {Indirizzo}  IT-00000 {Località}  Tel: + {Numero di telefono}  <{E-mail}> | **Suomi/Finland**  {Nimi/Namn}  {Osoite/Adress}  FI-00000 {Postitoimipaikka/Stad}  Puh/Tel: + {Puhelinnumero/Telefonnummer}  <{E-mail}> |
| **Κύπρος**  {Όνομα}  {Διεύθυνση}  CY-000 00 {πόλη}  Τηλ: + {Αριθμός τηλεφώνου}  <{E-mail}> | **Sverige**  {Namn}  {Adress}  SE-000 00 {Stad}  Tel: + {Telefonnummer}  <{E-mail}> |
| **Latvija**  {Nosaukums}  {Adrese}  {Pilsēta}, LV{Pasta indekss }  Tel: + {Telefona numurs}  <{E-mail}> | **United Kingdom (Northern Ireland)**  {Name}  {Address}  {Town} {Postal code} – UK  Tel: + {Telephone number}  <{E-mail}>> |

**<17. Other information>**