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| **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET**  **{NATURE/TYPE}** |

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

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

**2. COMPOSITION**

**3. PACKAGE SIZE**

**4. TARGET SPECIES**

**5. INDICATIONS FOR USE**

**Indications for use**

**6. CONTRAINDICATIONS**

**Contraindications**

**7. SPECIAL WARNINGS**

**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:>

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

<Overdose:>

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

<Major incompatibilities:>

**8. ADVERSE EVENTS**

**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 on this label, 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><the local representative of the marketing authorisation holder> using the contact details on this label, or via your national reporting system {national system details}.>

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

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

**10.** **ADVICE ON CORRECT ADMINISTRATION**

**Advice on correct administration**

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

**11. WITHDRAWAL PERIODS**

**Withdrawal periods**

**12. SPECIAL STORAGE PRECAUTIONS**

**Special storage precautions**

Keep out of the sight and reach of children.

<Do not store above <25 °C> <30 °C>.> or

<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.>

**13. SPECIAL PRECAUTIONS FOR DISPOSAL**

**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.>

**14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

**Classification of veterinary medicinal products**

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

EU/0/00/000/000

**Pack sizes**

<Not all pack sizes may be marketed.>

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

**Date on which the label 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.

**17. CONTACT DETAILS**

**Contact details**

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

<Manufacturer responsible for batch release:>

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

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

|  |  |
| --- | --- |
| **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: +370{telefono numeris}  <{E-mail}> |
| **Република България**  {Наименование}  <{Адрес}  BG {Град} {Пощенски код}>  Teл: + 359 {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}  IE - {Town} {Code for Dublin}>  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}>> |

**18. OTHER INFORMATION**

**<Other information>**

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

For animal treatment only.

**20. EXPIRY DATE**

Exp {mm/yyyy}

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

<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: ….>

**21. BATCH NUMBER**

Lot {number}