

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

{NATURE/TYPE}

- *This template caters for the situation where applicants intend not to print a package leaflet and propose to accommodate all labelling + package leaflet information on the immediate packaging, which is foreseen by Art. 14(4) of Regulation (EU) 2019/6 concerning the package leaflet: "...the information required in accordance with this Article may, alternatively, be provided on the packaging of the veterinary medicinal product".*
- *The combined label-leaflet template can only be used when **all** the printed information is **directly visible** on the immediate container. If a fold-out (concertina) label/leaflet is proposed, the separate templates for labelling text and package leaflet shall be used.*
- *All information shall be clearly displayed on the printed label. Information given in sections 1, 3 and 4 must be displayed on the main panel and in the same field of vision as these are important items for correct and safe identification and avoidance of mix-ups of the veterinary medicinal product.*
- *Guidance given in the preamble of the labelling text and package leaflet templates should also be applied on the combined label-leaflet when applicable.*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

[As in SPC section 1]

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

[Name of the veterinary medicinal product followed by its strength (if applicable) and pharmaceutical form. Pharmaceutical form according to the full "Standard terms" published by the Council of Europe. If necessary, target species, in order to avoid any confusion over different presentations of the veterinary medicinal product (e.g. same active substance and invented name) in different formulations for different target species.]

2. COMPOSITION

[Qualitative and quantitative composition of the active substance or substances and of excipients and other constituents (e.g. adjuvants), knowledge of which is essential for proper administration of the veterinary medicinal product i.e. those listed quantitatively in section 2 of the SPC should be stated here.]

[Include a description of the visual appearance of the pharmaceutical form, as marketed e.g. shape, texture, colour, imprint. Also, include a description of the appearance of the product before reconstitution/dilution, if applicable.]

3. PACKAGE SIZE

[By weight, by volume, by number of immediate packaging units or by number of doses of the veterinary medicinal product (i.e. package size, including a reference to any ancillary items included in the pack such as needles, swabs; content of bottle etc.)]

[A short statement should be used to describe the package size:

e.g.

"10 ml" (not "10 ml vial")

"10 x 50 ml" (not "10 vials with 50 ml of solution for injection")]

[In case of a combined labelling text covering different package sizes of the same strength, further package size(s) should be included in grey shading.

e.g.

28 tablets
56 tablets
100 tablets]

4. TARGET SPECIES

[As in SPC section 3.1]

5. INDICATIONS FOR USE

Indications for use

[Indication(s) in each target species should be stated here, using understandable language. A short section describing clearly the benefits of the veterinary medicinal product and the purpose of the treatment should be stated here, using understandable language, in order to provide a good balance between information on the benefits of the product and its risks.]

6. CONTRAINDICATIONS

Contraindications

[Include information from section 3.3 of the SPC, if applicable.]

7. SPECIAL WARNINGS

Special warnings

[Relevant text from sections 3.4, 3.5, 3.7, 3.8, 3.10, 3.11 and 5.1 of the SPC should be included as appropriate in user-friendly wording.]

[Sub-headings should be used in this section to list warnings and precautions. For certain veterinary medicinal product not all sub-headings may be relevant, in this case the heading should not be included.]

[For warning on accidental self-administration, etc. include statement as it appears in the SPC section 3.5.]

<None.>

<Special warnings: *[for each target species, as per SPC section 3.4]*>

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

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

[If the veterinary medicinal product contains mineral oil, the warnings in the SPC should be repeated here.]

<Special precautions for the protection of the environment:>

[In accordance with SPC section 3.5, special precautions regarding impact on the environment and risk mitigation measures e.g. treated dogs should not be allowed to enter surface water for 48 hours after treatment to avoid adverse effects on aquatic organisms.]

<Other precautions:> *[E.g. chemical reactions of the VMP with furniture or clothes.]*

<Pregnancy:>

<Lactation:>

<Pregnancy and lactation:>

<Laying birds:>

<Fertility:>

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

<Overdose:>

[Symptoms of overdose and, where applicable, emergency procedures, antidotes]

<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.]

[Information from SPC section 3.11 appropriate to the package leaflet.]

<Major incompatibilities:>

8. ADVERSE EVENTS

Adverse events

[Adverse events should be coded using VeDDRA standard terms (preferably VeDDRA low level terms (LLTs) and ranked in “frequency groupings” with the most frequently occurring clinical signs listed first. In each frequency category, clinical signs should be grouped in accordance with VeDDRA system organ classes (SOC).]

{Target species:} [The relevant single or multiple target species to be specified]

[Adverse events may be presented as in the SPC, a singular column tabular format for each target species or only text in sections maintaining the headings and structure used in the SPC and described as follows.

Adverse events related to several target species may be merged if they are strictly the same or when there are a few adverse events which have a different frequency, which can be annotated in a footnote immediately below the table or section. Tabular rows or sections should be deleted if there are no adverse events in that frequency category].

[Example single column table below]

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

*[*Additional information should preferably be detailed in a footnote immediately under the table or section and should comprise information necessary for supporting adverse event management (i.e. administration of an antidote, removing of a collar, washing of an application site...). Where relevant, information on the expected severity, duration and outcome of the clinical signs that may result following administration of the veterinary medicinal product can be described (e.g. lameness, 1-3 weeks following booster vaccination; vomiting and/ or diarrhoea, generally lasting 2 days, etc).]
Where relevant, information on different frequencies of adverse events reported depending on indication and dosing can be specified (e.g. vomiting is reportedly rare when given at 10mg/kg dose). If a footnote is not used, then additional information should be briefly stated in parenthesis after the relevant clinical sign(s).]*

[Close this section with:]

<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

[Space shall be provided for the prescribed dose to be indicated on the label/outer carton. Routes of administration should be mentioned according to “Standard terms” published by the Council of Europe.]

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

[Directions for proper use of the veterinary medicinal product by healthcare professionals, farmer or animal owner; including practical details such as mixing instructions e.g. "Shake well before use". Relevant text from section 3.9 of the SPC should be included as appropriate in user-friendly wording. Detailed instructions for use, application and implantation, if necessary, with explanatory drawings and pictures. If the medicine contains or requires the use of devices for administration or implantation a description of those devices should be provided.]

[A description of appearance after reconstitution, if applicable. Where appropriate, warning against certain visible signs of deterioration:]

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

11. WITHDRAWAL PERIODS

Withdrawal periods

[As it appears in section 3.12 of the SPC.]

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

[As it appears in section 5.3 of the SPC.]

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

[Special precautions for the disposal of unused product or waste materials, if any. Include the information from section 5.5 of the SPC in user-friendly wording.]

[For MRP/DCP/SRP and national procedures: information on the national collection systems referred to in Article 117, applicable to this veterinary medicinal product, to be completed in accordance with national requirements after conclusion of the MRP/DCP/SRP. Additional national requirements may apply in some Member States and can be included here.]

[Special precautions and instructions for handling and disposal of used veterinary medicinal product or waste materials derived from such product if appropriate, with explanatory drawings and pictures (if necessary).]

<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.> *[if applicable.]*

<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.>

[The next sentence below should be included unless the veterinary medicinal product is for administration only by a veterinarian]

<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

[As it appears in section 10 of the SPC.]

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

[Item to be completed by the marketing authorisation holder once the marketing authorisation has been granted.]

[In case of a combined labelling text covering different package sizes of the same strength, the respective package size should be included in grey shading after the corresponding EU Sub-Number and listed on a separate line.

e.g.

EU/0/00/000/001 28 tablets

EU/0/00/000/002 56 tablets

EU/0/00/000/003 100 tablets]

EU/0/00/000/000

[For MRP/DCP/SRP and national procedures: Number allocated by the Member State. To be completed in accordance with national requirements after conclusion of the MRP/DCP/SRP.]

Pack sizes

[All pack sizes must be detailed here, as per section 5.4 of the SPC and indicating any devices supplied. E.g. Cardboard box with 1 x 15 ml bottle and an oral syringe, or cardboard box with 1 or 5 vial(s) of 50 ml or 100 ml. If the product only has one package size and it is stated in section 5, it can be repeated here in grey shading.]

[If applicable, add:] <Not all pack sizes may be marketed.>

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

[Leave blank in case of first authorisation].

[Item to be completed by the marketing authorisation holder at time of printing the label. Date of latest procedure changing the label:

- For variations not requiring assessment this date will correspond to the implementation date i.e. when the MAH internally approves the revised product information in its own quality system;*
- For variations requiring assessment, the date of amendment of the decision granting the marketing authorisation (or date of EMA notification amending the annexes to the marketing authorisation). For MRP/DCP and national procedures: to be completed in accordance with national requirements after conclusion of the procedure;*
- Or implementation date of the Urgent Safety Restriction, or implementation date of MA transfer.]*

<{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

[Name or company name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer responsible for batch release, if different. Local representatives to be included, where applicable]

[Including town, postal code (if available) and country name in the language of the text (telephone numbers, E-mail addresses may be included (no websites or E-mails linking to websites allowed).]

[For MRP/DCP/SRP and national procedures: To be completed nationally.]

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

[If there are no local representatives and the marketing authorisation holder is the contact point for the reporting of adverse reactions according to Article 14(1)(l) of Regulation (EU) 2019/6, then all necessary

contact details must be included here and the following must be included in the subheading: < and contact details to report suspected adverse reactions>.]

<Manufacturer responsible for batch release>:

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

[If the local representative is the contact point for the reporting of adverse reactions according to Article 14(1)(l) of Regulation (EU) 2019/6, then all necessary contact details must be included here and it must be included in the subheading: < 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.>

- *[Listing of local representatives is not a requirement, but where used they must be provided for all Member States. If included in the product information annexes, the full list for all Member States must be stated [not applicable for MRP/DCP/SRP and national procedures for which the local representative can be stated separately for each Member State during the national phase when translations of the product information are provided]. However, a representative may be designated for more than one country and may also be the MAH where no other local representative is indicated. In cases where the same representative is designated for more than one country, the representative's details may be listed only once below the names of the countries concerned.*
- *On the **printed** label, only the concerned local representative can be mentioned provided the whole list has been included in the product information annexes [not applicable for MRP/DCP/SRP and national procedures.*
- *Where a local representative is located outside the country concerned and where an address is given, the country name must be included in the address of the local representative and must be given in the language(s) of the country for which the local representative is designated.*
- *ISO country codes may be used to replace the full name of the country heading. ISO codes together with the respective names of EU/EEA countries can be found at the following web site: <http://publications.eu.int/code/en/en-370101.htm>.*
- *In order to save space on the printed label, local representatives may be presented sequentially rather than in a tabulated format. In case of multi-lingual leaflets, the list of local representatives can be printed only once on the label.*
- *The local representative may be indicated by name/company name, permanent address/registered place of business, telephone number and E-mail address (optional). Website addresses or E-mails linking to websites are not allowed.*
- *For Belgium and Finland addresses may appear in two languages, respectively Dutch/French and Finnish/Swedish.*
- *For Greece and Cyprus, the address must appear in Greek.*

Telephone numbers: international dialling code followed by the area code and telephone number, e.g. EMA Tel: +31 (0)88 781 6000]

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}>
Тел: + 359 {Телефонен номер}
<{E-mail}>

Česká republika

{Název}
<{Adresa}
CZ {město}>
Tel: +{telefonní číslo}
<{E-mail}>

Danmark

{Navn}
<{Adresse}
DK-0000 {by}>
Tlf: + {Telefonnummer}
<{E-mail}>

Deutschland

{Name}
<{Anschrift}
DE-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Eesti

{Nimi}
<{Aadress}
EE -{Postiindeks} {Linn}>
Tel: +{Telefoninumber}
<{E-mail}>

Ελλάδα

{Όνομα}
<{Διεύθυνση}
EL-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

España

{Nombre}
<{Dirección}
ES-00000 {Ciudad}>
Tel: + {Teléfono}
<{E-mail}>

Luxembourg/Luxemburg

{Nom}
<{Adresse}
L-0000 {Localité/Stadt}>
Tél/Tel: + {N° de téléphone/Telefonnummer}
<{E-mail}>

Magyarország

{Név}
<{Cím}
HU-0000 {Város}>
Tel.: + {Telefonszám}
<{E-mail}>

Malta

{Isem}
<{Indirizz}
MT-0000 {Belt/Raħal}>
Tel: + {Numru tat-telefon}
<{E-mail}>

Nederland

{Naam}
<{Adres}
NL-0000 XX {stad}>
Tel: + {Telefoonnummer}
<{E-mail}>

Norge

{Navn}
<{Adresse}
N-0000 {poststed}>
Tlf: + {Telefonnummer}
<{E-mail}>

Österreich

{Name}
<{Anschrift}
A-00000 {Stadt}>
Tel: + {Telefonnummer}
<{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}>

Hrvatska

{Ime}
 <{Adresa}>
 {Poštanski broj} {grad}>
 Tel: + {Telefonski broj}
 <{E-mail}>

Ireland

{Name}
 <{Address}>
 IE - {Town} {Code for Dublin}>
 Tel: + {Telephone number}
 <{E-mail}>

Ísland

{Nafn}
 <{Heimilisfang}>
 IS-000 {Borg/Bær}>
 Sími: + {Símanúmer}
 <{Netfang}>

Italia

{Nome}
 <{Indirizzo}>
 IT-00000 {Località}>
 Tel: + {Numero di telefono}>
 <{E-mail}>

Κύπρος

{Όνομα}
 <{Διεύθυνση}>
 CY-000 00 {πόλη}>
 Τηλ: + {Αριθμός τηλεφώνου}
 <{E-mail}>

Latvija

{Nosaukums}
 <{Adrese}>
 {Pilsēta}, LV {Pasta indekss }>
 Tel: + {Telefona numurs}
 <{E-mail}>

Portugal

{Nome}
 <{Morada}>
 PT-0000-000 {Cidade}>
 Tel: + {Número de telefone}
 <{E-mail}>

România

{Nume}
 <{Adresă}>
 {Oraș} {Cod poștal} – RO>
 Tel: + {Număr de telefon}
 <{E-mail}>

Slovenija

{Ime}
 <{Naslov}>
 SI-0000 {Mesto}>
 Tel: + {telefonska številka}
 <{E-mail}>

Slovenská republika

{Meno}
 <{Adresa}>
 SK-000 00 {Mesto}>
 Tel: + {Telefónne číslo}
 <{E-mail}>

Suomi/Finland

{Nimi/Namn}
 <{Osoite/Adress}>
 FI-00000 {Postitoimipaikka/Stad}>
 Puh/Tel: + {Puhelinnumero/Telefonnummer}
 <{E-mail}>

Sverige

{Namn}
 <{Adress}>
 SE-000 00 {Stad}>
 Tel: + {Telefonnummer}
 <{E-mail}>

United Kingdom (Northern Ireland)

{Name}
 <{Address}>
 {Town} {Postal code} – UK>
 Tel: + {Telephone number}
 <{E-mail}>

18. OTHER INFORMATION

<Other information>

[Pharmacological or immunological information and environmental properties (if applicable) could be included here.]

[For novel therapy veterinary medicinal products and other veterinary medicinal products on a case by case basis: Explanatory illustrations may be included if necessary.]

[In accordance with Article 14(2), the package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. That additional information shall appear in the package leaflet clearly separated from the information in the sections above.]

Any additional, national distribution categories should be completed here in accordance with national requirements after conclusion of the MR/DC/SR phase of the procedure (with reference to the RMS list 'Legal Status for the Supply': <https://spor.ema.europa.eu/rmswi/#/lists/100000072051/terms>). In case of multi-lingual labels, distribution categories should be clearly indicated per country using the country codes i.e. AT, BE, DE etc.

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

*[The expiry date preceded by the abbreviation “EXP” should be taken to mean the last day of that month. Expiry dates should be expressed with the month given as 2 digits and the year as 4 digits. e.g.02/2007]
[On a case by case basis, for novel therapy veterinary medicinal products and for biological veterinary medicinal products (e.g. with a shelf-life of < 2 years), the expiry date may specify the day i.e. dd/mm/yyyy.]*

Exp {mm/yyyy}

[Where applicable, shelf life after reconstitution, dilution or after first opening the container.]

<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

[The batch number, preceded by the word “Lot”]

Lot {number}