

| *[Version 8.1, 01/2017]* ~~*[Version 8, 10/2012]*~~

**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 substance<s>:**

<Adjuvant<s>:>

<Excipient<s>:>

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

## 4. CLINICAL PARTICULARS

### 4.1 Target species

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

<Onset of immunity: {x weeks}>

<Duration of immunity: {x years}>

### 4.3 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).>

### 4.4 Special warnings for each target species

<None.>

<Vaccinate healthy animals only.>

### 4.5 Special precautions for use

Special precautions for use in animals

<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 ~~litter~~ 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 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.>

<The long-term effects of the veterinary medicinal product on the population dynamics of dung beetles have not been investigated. Therefore, it is advisable not to treat animals on the same pasture every season.>

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

<The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s)) ~~during the course of one treatment~~)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).>

#### 4.7 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 accordingly 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 ~~onset~~ start of the laying period.>>

<Fertility:>

<Do not use in breeding animals.>

#### 4.8 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 product><vaccine><immunological veterinary medicinal product> 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).}>

#### **4.9 Amounts to be administered and administration route**

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

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

#### **4.11 Withdrawal period(s)**

<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.>

~~<Not authorised for use in birds producing eggs for human consumption, including replacement chicks which are intended to produce eggs for human consumption.>~~

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

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

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

Pharmacotherapeutic group: {group}.

ATC\_vet code: {lowest available level (e.g. subgroup for chemical substance)}.

#### **<5.1 Pharmacodynamic properties>**

#### **<5.2 Pharmacokinetic particulars>**

#### **<Environmental properties>**

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

## 6.2 Major Incompatibilities

<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 <diluent/solvent or other component> <recommended><supplied> <for use with the veterinary medicinal product>.>

<None known.>

## 6.3 Shelf life

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

<Shelf life after first opening the immediate packaging: >

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

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

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

## 6.4. 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.]*

## 6.5 Nature and composition of immediate packaging

<Not all pack sizes may be marketed.>

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

<Not applicable.>

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

<{Invented name} should not enter water courses as this may be dangerous for fish and other aquatic organisms.>

## 7. MARKETING AUTHORISATION HOLDER

{Name ~~and~~  
#Address  
Country}  
<{Tel.}>  
<{Fax}>  
<{E-mail}>

## 8. MARKETING AUTHORISATION NUMBER(S)

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

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

## 10 DATE OF REVISION OF THE TEXT

<{MM/YYYY}>  
<{DD/MM/YYYY}>  
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

## PROHIBITION OF SALE, SUPPLY AND/OR USE

<Not applicable.>

~~<The manufacture, import, possession, sale, supply and/or use of {invented name} may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use <invented name> must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.>~~

<Any person intending to manufacture, import, possess, 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.>

<Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.>



**ANNEX II***[Not applicable for MRP/DCP]*

- A. <MANUFACTURER<S> OF THE BIOLOGICAL ACTIVE SUBSTANCE<S> AND<S> MANUFACTURER<S> RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**
- <D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION>**

**A. <MANUFACTURER<S> OF THE BIOLOGICAL ACTIVE SUBSTANCE<S> AND<S> MANUFACTURER<S> RESPONSIBLE FOR BATCH RELEASE**

<Name and address of the manufacturer<s> of the biological active substance<s>

{Name and address}>

Name and address of the manufacturer<s> responsible for batch release

{Name and address}

<The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.>

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

<Veterinary medicinal product subject to prescription.>

<Veterinary medicinal product not subject to prescription.>

<According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

- a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.
- b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.>

<Official control authority batch release is required for this product.> *[only for those immunological veterinary medicinal products which are listed for [Official Control Authority Batch Release \(OCABR\)](#) in accordance with Article 82 of Directive 2001/82/EC as amended.]*

**C. STATEMENT OF THE MRLs**

<Not applicable.>

*[For pharmaceutical products]*

The active substance<s> in {name of the product} <is><are> <an> allowed substance<s> as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification

<The excipients listed in section 6.1 of the SPC are <either> <allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required> <or> <considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product>.>

*[In case of MRLs not been published yet]*

The Committee for Medicinal Products for Veterinary Use has recommended the inclusion of {name of the active substance(s)} in {name of the product} in table 1 (Allowed substances) of the annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification

<The excipients, listed in section 6.1 of the SPC are <either> <allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required> <or> <considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product>.>

*[For immunological products]*

The active substance being a principle of biological origin intended to <produce> <active><passive><diagnose a state of> immunity is not within the scope of Regulation (EC) No 470/2009.

<The excipients (including adjuvants) listed in section 6.1 of the SPC are <either> <allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required> <or> <considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product>.>

#### **<D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

<Specific pharmacovigilance requirements:>

<The periodic safety update report (PSUR) cycle should be restarted for submission of 6 monthly reports (covering all authorised presentations of the product) for the next two years, followed by yearly reports for the subsequent two years and thereafter at 3 yearly intervals. [The data look point \(DLP\) for the next PSUR would be {add DLP}](#).>*[Only applicable, if justified after authorisation.]*

#### **• CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

[<Not applicable.>](#)

[<For use by veterinary surgeons only.>](#)

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

<This being an approval under exceptional circumstances and pursuant to Article 39(7) of Regulation (EC) No 726/2004, 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:

<b>Description</b>	<b>Due date</b>

>>

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>**

{NATURE/TYPE}

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

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

**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**

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

<Withdrawal period(s): >

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

<Read the package leaflet before use.>

<Accidental injection is dangerous.>

<<Accidental administration> <Contact with the mucosa> is dangerous.>

**10. EXPIRY DATE**

*[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website*

*[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2014/08/WC500170559.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf)*

*[http://www.emea.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2009/10/WC500004426.pdf](http://www.emea.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf)*

<EXP {month/year}>  
<Once <broached><opened><diluted><reconstituted> <use by...><use within...> <use immediately>.>

## 11. SPECIAL 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.>

*[\* 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.).*

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

<Dispose of waste material in accordance with local requirements.>

<Disposal: read package leaflet.>

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

For animal treatment only. <To be supplied only on veterinary prescription.>

<The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.>

<Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.>

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



Keep out of the sight and reach of children.

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

{Name-~~and~~  
Address  
Country. }  
<{Tel.}>  
<{Fax}>  
<{E-mail}>

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

EU/2/00/000/000

**17. MANUFACTURER'S BATCH NUMBER**

*[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website*

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2014/08/WC500170559.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf)

[http://www.emea.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2009/10/WC500004426.pdf](http://www.emea.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf)

<Batch><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 <strength> pharmaceutical form <target species> }  
{active substance(s)}

**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(S)**

<Withdrawal period(s): >

**6. BATCH NUMBER**

*For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website*

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2014/08/WC500170559.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2009/10/WC500004426.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf)

<Batch><Lot> {number}

**7. EXPIRY DATE**

*For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website*

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2014/08/WC500170559.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2009/10/WC500004426.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf)

<EXP {month/year}>

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

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

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

{NATURE/TYPE}

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

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

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

{Name}

**3. EXPIRY DATE**

*[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website*

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2014/08/WC500170559.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf)

[http://www.emea.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2009/10/WC500004426.pdf](http://www.emea.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf)

<EXP {month/year}>

**4. BATCH NUMBER**

*[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website*

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2014/08/WC500170559.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf)

[http://www.emea.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2009/10/WC500004426.pdf](http://www.emea.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf)

<Batch><Lot> {number}

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

For animal treatment only.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET ~~FOR~~:**

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

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

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Marketing authorisation holder <and manufacturer responsible for batch release>:

<Manufacturer responsible for batch release:>

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

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

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

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**4. INDICATION(S)**

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**5. CONTRAINDICATIONS**

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**6. ADVERSE REACTIONS**

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<The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s)) ~~during the course of one treatment~~
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).>

~~If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.~~

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 inform your veterinary surgeon.

<Alternatively you can report via your national reporting system {national system details}.> [For MRP/DCP only]

**7. TARGET SPECIES**

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

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**9. ADVICE ON CORRECT ADMINISTRATION**

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<Do not use {name of product} if you notice {description of the visible signs of deterioration}.>

## 10. WITHDRAWAL PERIOD(S)

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## 11. SPECIAL STORAGE PRECAUTIONS

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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 {abbreviation used for expiry date}>. <The expiry date refers to the last day of that month.>

<Shelf life after first opening the container: ....>

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

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

## 12. SPECIAL WARNING(S)

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<None.>

<Special warnings for each target species:>

<Special precautions for use in animals:>

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

<Pregnancy:>

<Lactation:>

<Pregnancy and lactation:>

<Lay:>

<Fertility:>

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

<Overdose (symptoms, emergency procedures, antidotes):>

<Incompatibilities:>

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

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

<Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required. These measures should help to protect the environment.>

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

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Detailed information on this [veterinary medicinal](#) product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

### **<15. OTHER INFORMATION>**

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<Not all pack sizes may be marketed.>

<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: +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}>

**France**

{Nom}  
<{Adresse}  
FR-00000 {Localité}>  
Tél: + {Numéro de téléphone}  
<{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}>

**Portugal**

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

**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**

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