[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procapen, 300 mg/ml, Suspension for injection for cattle, pigs and horses [BG, CY, CZ, DE, DK, EE, EL, ES, FI, HU, IT, LV, LT, MT, NL, PL, PT, RO, SK]
Livipen, 300 mg/ml, Suspension for injection for cattle, pigs and horses [AT, SI]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:
Benzylpenicillin, procaine monohydrate 300.00 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E 218)	2.84 mg
Propyl parahydroxybenzoate	0.32 mg
Sodium thiosulfate	1.00 mg
Lecithin	
Povidone K 25	
Sodium citrate	
Propylene glycol	
Disodium edetate	
Potassium dihydrogen phosphate	
Water for injections	

White to yellowish suspension

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs (adult pigs) and horses

3.2 Indications for use for each target species

For the treatment of bacterial infectious diseases, caused by pathogens susceptible to benzylpenicillin.

Cattle, calves, and horses:
General bacterial infections (septicaemias)
Infections of the
- respiratory system
- urinary and genital apparatus
- skin, claws and hooves
- joints

Pigs (adult pigs):
Infections of the

- urogenitary tract (infections with beta-haemolytic *Streptococcus* spp.)
- musculoskeletal system (infections with *Streptococcus suis*)
- skin (infections with *Erysipelotrix rhusiopathiae*)

3.3 Contraindications

Do not use in cases of:
- hypersensitivity to penicillins or cephalosporins, the active substances or to any of the excipients
- severe disturbances of kidney functions with anuria or oliguria

Do not administer intravenously.

3.4 Special warnings

After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the veterinary medicinal product for treatment of meningitis or CNS infections due to e.g., *Streptococcus suis* or *Listeria monocytogenes* may not be efficacious. Furthermore, benzylpenicillin penetrates mammalian cells poorly and hence this veterinary medicinal product may have little effect in treating intracellular pathogens e.g., *Listeria monocytogenes*.

Elevated MIC values or bi-modal distribution profiles suggesting acquired resistance have been reported for the following bacteria:
- *Streptococcus* spp. and *S. suis* in pigs;
- *Fusobacterium necrophorum* causing metritis and *Mannheimia haemolytica* (only in some member states), as well as *Bacteroides* spp., *Staphylococcus chromogenes*, *Actinobacillus lignieresii* and *Trueperella pyogenes* in cattle.

Use of the veterinary medicinal product may result in a lack of clinical efficacy when treating infections caused by these bacteria.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the benzylpenicillin and may decrease the effectiveness of treatment with other penicillins and selected cephalosporins due to the potential for cross resistance.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this veterinary medicinal product if you know you are sensitised to penicillins or cephalosporins or if you have been advised not to work with such preparations.
Handle this veterinary medicinal product with great care to avoid self-injection and exposure by accidental contact with the skin or eyes. Persons developing a reaction after contact with the veterinary medicinal product should avoid handling the product (and other penicillin and cephalosporin containing products) in future.

It is recommended to wear gloves when handling or administering the veterinary medicinal product. Wash exposed skin after use. In case of any eye contact, wash the eyes thoroughly with copious amounts of clean running water.
If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic reaction[1], anaphylactic shock[2]

[1] in penicillin-sensitive animals
[2] because of the excipient polyvidone

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic reaction[1]
Undetermined frequency (cannot be estimated from the available data)	Restlessness[3] Convulsion[3], incoordination[3], muscle tremor[3]

[1] in penicillin-sensitive animals
[3] because of the active substance procaine, in rare cases with fatal outcome

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic reaction[1] Haemolytic anaemia, thrombocytopenia Cough Injection site swelling Abortion Elevated temperature[4], inappentence[4] Trembling[4], incoordination[4], Vomiting[4]

[1] in penicillin-sensitive animals
[4] signs of intolerance; may occur within 24 hours after injection which may be caused by the release of procaine

In case of side effects, the animal has to be treated symptomatically.

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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

The bactericidal efficacy of penicillin pose antagonism with bacteriostatic antimicrobials such as macrolides and tetracyclines and synergism with aminoglycosides.

The excretion of benzylpenicillin is extended due to phenylbutazon and acetylsalicylacid.
Inhibitors of the cholinesterase delay the degradation of procain.

3.9 Administration routes and dosage

Intramuscular use.
Shake well before use.

Cattle:
20 mg benzylpenicillin, procaine per kg bodyweight,
Corresponding to 1 ml of the veterinary medicinal product for 15 kg bodyweight.
Per each injection site not more than 20 ml of injectable suspension should be applied.

Calves:
15 - 20 mg benzylpenicillin, procaine per kg bodyweight
corresponding to 0.75 - 1 ml of the veterinary medicinal product for 15 kg bodyweight.
Per each injection site not more than 20 ml of injectable suspension should be applied.

Pigs:
20 mg benzylpenicillin, procaine per kg bodyweight
corresponding to 1 ml of the veterinary medicinal product for 15 kg bodyweight.
Per each injection site not more than 10 ml of injectable suspension should be applied.

Horses:
15 mg benzylpenicillin, procaine per kg bodyweight
corresponding to 0.5 ml of the veterinary medicinal product for 10 kg bodyweight.
Per each injection site not more than 20 ml of injectable suspension should be applied.

Administer alternatively on the left and right side.

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

The treatment duration is 3 to 7 days, one injection to be administered every 24 hours.
The appropriate treatment duration should be chosen based on the clinical needs and individual recovery of the treated animal. Consideration should be given to the accessibility of the target tissue and characteristics of the target pathogen.
A clinical response is normally observed within 24 hours.

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

In the case of overdosing central nervous excitations and convulsions may occur. The use of the veterinary medicinal product has to be terminated immediately and a symptomatic treatment (e.g. barbiturates) should be initiated.
A premature termination of the treatment with this veterinary medicinal product should be done only after consultation of the veterinarian to avoid the development of resistant bacterial strains.

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

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal 14 days for treatment duration 3 days
16 days for treatment duration 4-7 days
Milk 6 days

Pigs (adult pigs):
Meat and offal 15 days for treatment duration 3 days
17 days for treatment duration 4-7 days

Horse:
Meat and offal 14 days for treatment duration 3 days
16 days for treatment duration 4-7 days
Not authorised for use in mares producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QJ01CE09

4.2 Pharmacodynamics

Benzylpenicillin, procaine is a depot penicillin which is not easily dissolved in water and which releases benzylpenicillin and procaine in the organism by means of dissociation. The free benzylpenicillin is primarily effective against gram-positive pathogens. Penicillins have a bactericidal effect on proliferating pathogens by inhibiting cell wall synthesis. Benzylpenicillin is acid-labile and is inactivated by bacterial beta-lactamases. Enterobacterales, *Bacteroides fragilis*, most *Campylobacter* spp., *Nocardia* spp. and *Pseudomonas spp*. as well as beta-lactamase–producing *Staphylococcus* spp. are resistant.

The clinical breakpoints for Benzylpenicillin (Penicillin G) proposed in 2015 by CLSI (Clinical and Laboratory Standards Institute) can be summarised as follows:

	Target species	**Tissue**	**Clinical Breakpoints (µg/ml)**		
			Susceptible	**Intermediate**	**Resistant**
Streptococcus suis	Pig	-	≤ 0.25	0.5	≥ 1

Mechanisms of resistance:
The most frequent mechanism of resistance is production of beta-lactamases (more specifically penicillinase especially in *S.* aureus), which cleave the beta-lactam ring of penicillins making them inactive. Modification of penicillin-binding proteins is another mechanism of acquired resistance

4.3 Pharmacokinetics

As benzylpenicillin procaine is a depot penicillin, absorption is delayed when compared to easy water soluble penicillin salts and therapeutic serum levels are maintained over a prolonged period.

In pigs, maximum serum levels are reached within 30 min after parenteral injection of benzylpenicillin procaine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product in one syringe because of possible chemical-physical incompatibilities.
Water-soluble penicillins are not compatible with metal ions, aminoacids, ascorbin acid, heparin and the vitamins of the B-complex.

5.2 Shelf life

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

Glass bottle:	4 years
PP-bottle:	3 years
Shelf-life after first opening the immediate packaging:	28 days

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C)
Keep the container in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Siliconised vial of glass type II/ PP-bottle with bromobutyl rubber stopper and aluminium flip-off seal in a cardboard box.

Pack sizes:
1 x 100 ml vial/bottle
1 x 250 ml vial/bottle
12 x 100 ml vials/bottles
12 x 250 ml vials/bottles

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.

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

aniMedica GmbH

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}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{ Box }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procapen, 300 mg/ml, Suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Active substance:
Benzylpenicillin, procaine monohydrate 300.00 mg

3. PACKAGE SIZE

100 ml
12 x 100 ml
250 ml
12 x 250 ml

4. TARGET SPECIES

Cattle, pigs (adult pigs) and horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle**:**

Meat and offal	14 days for treatment duration 3 days 16 days for treatment duration 4-7 days
Milk	6 days

Pigs (adult pigs):

Meat and offal	15 days for treatment duration 3 days 17 days for treatment duration 4-7 days

Horse:

Meat and offal	14 days for treatment duration 3 days 16 days for treatment duration 4-7 days

Not authorised for use in mares producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C)
Keep the container in the outer carton in order to protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.
Shake well 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

aniMedica GmbH

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Vial, bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procapen, 300 mg/ml, Suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Active substance:
Benzylpenicillin, procaine monohydrate 300.00 mg

3. TARGET SPECIES

Cattle, pigs (adult pigs) and horses

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Shake well before use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle**:**

Meat and offal	14 days for treatment duration 3 days 16 days for treatment duration 4-7 days
Milk	6 days

Pigs (adult pigs):

Meat and offal	15 days for treatment duration 3 days 17 days for treatment duration 4-7 days

Horse:

Meat and offal	14 days for treatment duration 3 days 16 days for treatment duration 4-7 days

Not authorised for use in mares producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached, use by…

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C).
Keep the container in the outer carton to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Procapen, 300 mg/ml, Suspension for injection for cattle, pigs and horses

2. Composition

Each ml contains

Active substance:
Benzylpenicillin, procaine monohydrate 300.00 mg

Excipients:
Methyl parahydroxybenzoate (E 218) 2.84 mg
Propyl parahydroxybenzoate 0.32 mg
Sodium thiosulfate 1.00 mg

White to yellowish suspension.

3. Target species

Cattle, pigs (adult pigs) and horses

4. Indications for use

For the treatment of bacterial infectious diseases, caused by pathogens susceptible to benzylpenicillin.

Cattle, calves, and horses:
General bacterial infections (septicaemias)
Infections of the
- respiratory system
- urinary and genital apparatus
- skin, claws and hooves
- joints

Pigs (adult pigs):
Infections of the
- urogenitary tract (infections with beta-haemolytic *Streptococcus* spp.)
- musculoskeletal system (infections with *Streptococcus suis*)
- skin (infections with *Erysipelotrix rhusiopathiae*)

5. Contraindications

Do not use in cases of:
- hypersensitivity to penicillins or cephalosporins, the active substances or to any of the excipients
- severe disturbances of kidney functions with anuria or oliguria

Do not administer intravenously.

6. Special warnings

Special warnings:
After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the veterinary medicinal product for treatment of meningitis or CNS infections due to e.g., *Streptococcus suis* or *Listeria monocytogenes* may not be

efficacious. Furthermore, benzylpenicillin penetrates mammalian cells poorly, hence this veterinary medicinal product may have little effect in treating intracellular pathogens e.g., *Listeria monocytogenes*.

Elevated MIC values or bi-modal distribution profiles suggesting acquired resistance have been reported for the following bacteria:
- *Streptococcus* spp. and *S. suis* in pigs;
- *Fusobacterium necrophorum* causing metritis and *Mannheimia haemolytica* (only in some member states), as well as *Bacteroides* spp., *Staphylococcus chromogenes*, *Actinobacillus lignieresii* and *Trueperella pyogenes* in cattle.

Use of the veterinary medicinal product may result in a lack of clinical efficacy when treating infections caused by these bacteria.

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the benzylpenicillin and may decrease the effectiveness of treatment with other penicillins and selected cephalosporins due to the potential for cross resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this veterinary medicinal product if you know you are sensitised to penicillins or cephalosporins or if you have been advised not to work with such preparations.
Handle this veterinary medicinal product with great care to avoid self-injection and exposure by accidental contact with the skin or eyes. Persons developing a reaction after contact with the veterinary medicinal product should avoid handling the product (and other penicillin and cephalosporin containing products) in future.
It is recommended to wear gloves when handling or administering the veterinary medicinal product. Wash exposed skin after use. In case of any eye contact, wash the eyes thoroughly with copious amounts of clean running water.
If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
The bactericidal efficacy of penicillin pose antagonism with bacteriostatic antimicrobials such as macrolides and tetracyclines and synergism with aminoglycosides.

The excretion of benzylpenicillin is extended due to phenylbutazon and acetylsalicylacid.
Inhibitors of the cholinesterase delay the degradation of procain.

Overdose:

In the case of overdosing central nervous excitations and convulsions may occur. The use of the veterinary medicinal product has to be terminated immediately and a symptomatic treatment (e.g. barbiturates) should be initiated.
A premature termination of the treatment with this veterinary medicinal product should be done only after consultation of the veterinarian to avoid the development of resistant bacterial strains.

Major incompatibilities:
Do not mix with any other veterinary medicinal product in one syringe because of possible chemical-physical incompatibilities.
Water-soluble penicillins are not compatible with metal ions, aminoacids, ascorbin acid, heparin and the vitamins of the B-complex.

7. Adverse events

Cattle:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Allergic reaction[1], anaphylactic shock[2]

[1] in penicillin-sensitive animals
[2] because of the excipient polyvidone

Horses:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Allergic reaction[1]

Undetermined frequency (cannot be estimated from the available data)
Restlessness[3]
Convulsion[3], incoordination[3], muscle tremor[3]

[1] in penicillin-sensitive animals
[3] because of the active substance procaine, in rare cases with fatal outcome.

Pigs:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Allergic reaction[1]
Haemolytic anaemia, thrombocytopenia
Cough
Injection site swelling
Abortion
Elevated temperature[4], inappetence[4]
Trembling[4], incoordination[4]
Vomiting[4]

[1] in penicillin-sensitive animals
[4] signs of intolerance; may occur within 24 hours after injection which may be caused by the release of procaine

In case of side effects, the animal has to be treated symptomatically.

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Intramuscular use.

Cattle:
20 mg Benzylpenicillin, procaine per kg bodyweight
corresponding to 1 ml of the veterinary medicinal product for 15 kg bodyweight.
Per each injection site not more than 20 ml of injectable suspension should be applied.

Calves:
15 - 20 mg benzylpenicillin, procaine per kg bodyweight
corresponding to 0.75 - 1 ml of the veterinary medicinal product for 15 kg bodyweight.
Per each injection site not more than 20 ml of injectable suspension should be applied.

Pigs:
20 mg benzylpenicillin, procaine per kg bodyweight
corresponding to 1 ml of the veterinary medicinal product for 15 kg bodyweight.
Per each injection site not more than 10 ml of injectable suspension should be applied.

Horses:
15 mg benzylpenicillin, procaine per kg bodyweight
corresponding to 0.5 ml of the veterinary medicinal product for 10 kg bodyweight.
Per each injection site not more than 20 ml of injectable suspension should be applied.
Administer alternatively on the left and right side.

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

The treatment duration is 3 to 7 days , one injection to be administered every 24 hours.
The appropriate treatment duration should be chosen based on the clinical needs and individual recovery of the treated animal. Consideration should be given to the accessibility of the target tissue and characteristics of the target pathogen.
A clinical response is normally observed within 24 hours.

9. Advice on correct administration

Shake well before use.

10. Withdrawal periods

Cattle:

Meat and offal	14 days for treatment duration 3 days
	16 days for treatment duration 4-7 days
Milk	6 days

Pigs (adult pigs):

Meat and offal	15 days for treatment duration 3 days
	17 days for treatment duration 4-7 days

Horse:
Meat and offal 14 days for treatment duration 3 days
16 days for treatment duration 4-7 days

Not authorised for use in mares producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Keep the container in the outer carton in order to protect from light.

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

Shelf-life after first opening the immediate packaging: 28 days

12. Special precautions for disposal

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

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

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
1 x 100 ml vial/bottle in a cardboard box
1 x 250 ml vial/bottle in a cardboard box
12 x 100 ml vials/bottles in a cardboard box
12 x 250 ml vials/bottles in a cardboard box

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/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 contact details to report suspected adverse reactions:
aniMedica GmbH

Im Südfeld 9
48308 Senden-Bösensell
Germany
Tel: +49-2536-3302-0

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industrial Veterinaria, S.A.
Esmeralda 19
08950 Esplugues de Llobregat (Barcelona)
Spain

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Local representative and contact details to report suspected adverse reactions: