[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Taneven 300 mg/ml suspension for injection for horses, cattle, sheep, goats, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Benzylpenicillin (procaine) monohydrate (equivalent to benzylpenicillin 170 mg)	300.0 mg

Excipients:

Methyl parahydroxybenzoate (E 218)	2.84 mg
Propyl parahydroxybenzoate	0.32 mg
Sodium thiosulfate pentahydrate (E 539)	1.00 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection
White to slightly beige homogenous suspension

4. CLINICAL PARTICULARS

4.1 Target species

Horses, cattle, sheep, goats, dogs and cats

4.2 Indications for use, specifying the target species

For the treatment of the following infections caused by bacteria susceptible to benzylpenicillin:

- infections of the respiratory system
- infections of the urinary and reproductive system
- infections of the skin and claws
- infections of the joints
- septicaemia

4.3 Contraindications

Do not use
- in known cases of resistance to penicillin or cephalosporin
- in known cases of hypersensitivity to penicillins, cephalosporins, procaine or any of the excipients
- in known cases of severe renal dysfunction with anuria or oliguria
- in known cases of infections with ß-lactamase producing pathogens
- in rabbits, guinea pigs, hamsters and other small herbivores

Do not administer intravenously.

4.4 Special warnings for each target species

In competitive sport horses, it should be taken into account with regard to doping controls that the rapid dissociation of benzylpenicillin procaine may cause measurable procaine levels in urine and blood.
Complete cross-resistance has been shown between Benzylpenicillin procaine and other penicillins. Use of the product should be carefully considered when antimicrobial susceptibility testing has shown resistance to penicillins because its effectiveness may be reduced.

After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the 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 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:
- *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;
- *S. aureus*, coagulase negative *Staphylococci* and *Enterococcus* spp. in dogs;
- *Staphylococcus aureus* and *Staphylococcus felis* in cats.

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

4.5 Special precautions for use

Special precautions for use in animals
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other penicillins and 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 product if you know you are sensitised to penicillins or cephalosporins, or if you have been advised not to work with such preparations. Persons developing a reaction after contact with the product should avoid handling the product and other penicillin and cephalosporin containing products in future.

Handle this product with great care to avoid self-injection and exposure by accidental contact with the skin or eyes, taking all recommended precautions.

In case of accidental eye contact, rinse thoroughly with water. In case of accidental skin contact wash exposed skin thoroughly with soap and water.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

4.6 Adverse reactions (frequency and seriousness)
Benzylpenicillin procaine may cause hypersensitivity reactions to penicillin (ranging from allergic skin reactions to anaphylaxis).

Some horses may show signs of anxiety, loss of coordination and muscle tremor after use of benzylpenicillin procaine, potentially leading to death.

Anaphylactic reactions may occur in rare cases in cattle and dogs, due to the povidone content.

In rare cases local irritation at the injection site may occur. The probability of those adverse reactions can be reduced by decreasing the volume per injection site (please see also section "Amounts to be administered and administration route").

Counter measures:

In case of anaphylaxis:	Epinephrine (adrenalin) and glucocorticoids i.v.
For allergic skin reactions:	Antihistamines and / or glucocorticoids

In case of allergic reaction, treatment with the veterinary medicinal product should be discontinued immediately.

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

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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

Laboratory studies in animals have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use during pregnancy and lactation only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Natural penicillin is not compatible with metal ions, amino acids, ascorbic acid, heparin and vitamins of the B-complex. There is a potential antagonism of penicillin and chemotherapeutics regarding the bactericidal efficacy with a rapid onset of bacteriostatic effect. The excretion of benzylpenicillin is extended by probenecid, NSAIDs, sulfapyrazone and indomethacin. Inhibitors of the cholinesterase delay the degradation of procaine.

4.9 Amounts to be administered and administration route

For intramuscular or subcutaneous use.
The treatment duration is 3 to 7 days.
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.

Dogs, cats:
20 – 50 mg benzylpenicillin procaine per kg body weight (bw) (corresponding to 11.7 – 29.1 mg benzylpenicillin per kg body weight)
corresponding to 1 – 2.5 ml of the veterinary medicinal product per 15 kg bw.
At least 3 treatments at 24 hour intervals.

Cattle, sheep, goats:
20 mg benzylpenicillin procaine per kg body weight (bw) (corresponding to 11.7 mg benzylpenicillin per kg body weight) corresponding to 1 ml of the veterinary medicinal product per 15 kg bw.
At least 3 treatments at 24 hour intervals.

Horses:
15 mg benzylpenicillin procaine per kg body weight (bw) (corresponding to 8.7 mg benzylpenicillin per kg bodyweight) corresponding to 0.75 ml of the veterinary medicinal product per 15 kg bw.
At least 3 treatments at 24 hour intervals.

Or

20 mg benzylpenicillin procaine per kg body weight (bw) (corresponding to 11.7 mg benzylpenicillin per kg body weight) corresponding to 1 ml of the veterinary medicinal product per 15 kg bw.
At least two treatments at 48 hour intervals.

Bacterial susceptibility should be tested.

Since repeated injections are required in a treatment cycle, varying injection sites should be used. The maximum application volume of the veterinary medicinal product per injection site is 20 ml.To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
Shake well before use.

The stopper can be safely punctured up to 20 times.

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

In the case of overdosing central nervous excitations and convulsions may occur. The use of the product has to be terminated immediately and a symptomatic treatment (with benzodiazepines or barbiturates) should be initiated.

4.11 Withdrawal period(s)

Horse:

Meat and offal	10 days

Not authorised for use mares producing milk for human consumption.

Cattle, sheep and goat:

Meat and offal	10 days
Milk	120 hours (5 days)

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Beta-lactamase sensitive penicillins
ATC vet code: QJ01CE09.

5.1 Pharmacodynamic properties

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 ß-lactamases.
Enterobacterales, *Bacteroides fragilis*, most *Campylobacter* spp., *Nocardia* spp. and *Pseudomonas* spp. as well as beta-lactamase–producing *Staphylococcus* spp. are resistant.

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.

5.2 Pharmacokinetic particulars

Benzylpenicillin procaine is absorbed slowly after parenteral administration compared to the more water-soluble penicillin salts, which means that therapeutically effective serum levels, after administration of adequate doses, are achieved over a period of 24 – 36 hours. The half-life of benzylpenicillin procaine is about 5 hours after intramuscular injection in cattle, about 6 hours in calf and about 18 hours in horses. The elimination of benzylpenicillin is predominantly renal.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate
Lecithin
Propylene glycol
Povidone K25
Disodium edetate dihydrate
Sodium citrate dihydrate
Potassium dihydrogen phosphate
Sodium thiosulfate pentahydrate (E539)
Water for injection

6.2 Major incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life
Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 28 days

6.4. Special precautions for storage
Store in a refrigerator (2 °C – 8 °C).

6.5 Nature and composition of immediate packaging
100 ml clear glass vials (type II) with bromobutyl rubber stopper and aluminium cap in a cardboard box.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemensstr. 14
30827 Garbsen
Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{100 ml glass vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Taneven 300 mg/ml suspension for injection for horses, cattle, sheep, goats, dogs and cats

Benzylpenicillin (procaine) monohydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Benzylpenicillin (procaine) monohydrate 300 mg
(equivalent to benzylpenicillin 170 mg)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, cattle, sheep, goats, dogs and cats

6. INDICATION(S)

[not applicable]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or subcutaneous use.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Horse:
Meat and offal 10 days
Not authorised for use mares producing milk for human consumption.

Cattle, sheep and goat:
Meat and offal 10 days
Milk 120 hours (5 days)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days
Once opened use by…

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.

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

[Not requested on the immediate label.]

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.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

[Not requested on the immediate label.]

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemensstr. 14
30827 Garbsen
Germany

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box with 1 x 100 ml glass vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Taneven 300 mg/ml suspension for injection for horses, cattle, sheep, goats, dogs and cats

Benzylpenicillin (procaine) monohydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Benzylpenicillin (procaine) monohydrate 300 mg
(equivalent to benzylpenicillin 170 mg)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, cattle, sheep, goats, dogs and cats

6. INDICATION(S)

[not applicable]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or subcutaneous use.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Horse:
Meat and offal 10 days
Not authorised for use mares producing milk for human consumption.

Cattle, sheep and goat:
Meat and offal 10 days
Milk 120 hours (5 days)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days
Once opened use by…

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.

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

Disposal:
Read the package leaflet before use.

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.

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

WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemensstr. 14
30827 Garbsen
Germany

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Taneven 300 mg/ml suspension for injection for horses, cattle, sheep, goats, dogs and cats

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

Marketing authorisation holder and manufacturer responsible for batch release:
WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemensstr. 14
30827 Garbsen
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Taneven 300 mg/ml suspension for injection for horses, cattle, sheep, goats, dogs and cats
Taneven suspension for injection for horses, cattle, sheep, goats, dogs and cats (FR)

Benzylpenicillin (procaine) monohydrate

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

Each ml contains:

Active substance:

Benzylpenicillin (procaine) monohydrate (equivalent to benzylpenicillin 170 mg)	300.0 mg

Excipients:

Methyl parahydroxybenzoate (E218)	2.84 mg
Propyl parahydroxybenzoate	0.32 mg
Sodium thiosulfate pentahydrate (E 539)	1.00 mg

White to slightly beige homogenous suspension.

4. INDICATION(S)

For the treatment of the following infections caused by bacteria susceptible to benzylpenicillin:

- infections of the respiratory system
- infections of the urinary and reproductive system
- infections of the skin and claws
- infections of the joints
- septicaemia

5. CONTRAINDICATIONS

Do not use
- in known cases of resistance to penicillin or cephalosporin
- in known cases of hypersensitivity to penicillins, cephalosporins, procaine or any of the excipients
- in own cases of severe renal dysfunction with anuria or oliguria
- in own cases of infections with ß-lactamase producing pathogens

- in rabbits, guinea pigs, hamsters and other small herbivores

Do not administer intravenously.

6. ADVERSE REACTIONS

Benzylpenicillin procaine may cause hypersensitivity reactions to penicillin (ranging from allergic skin reactions to anaphylaxis).

Some horses may show signs of anxiety, loss of coordination and muscle tremor after use of benzylpenicillin procaine, potentially leading to death.

Anaphylactic reactions may occur in rare cases in cattle and dogs, due to the povidone content.

In rare cases local irritation at the injection site may occur. The probability of those adverse reactions can be reduced by decreasing the volume per injection site (please see also section "Amounts to be administered and administration route").

Counter measures

In case of anaphylaxis:	Epinephrine (adrenalin) and glucocorticoids i.v.
For allergic skin reactions:	Antihistamines and / or glucocorticoids

In case of allergic reaction, treatment with the veterinary medicinal product should be discontinued immediately.

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

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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 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}.

7. TARGET SPECIES

Horses, cattle, sheep, goats, dogs and cats

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

For intramuscular or subcutaneous use.
The treatment duration is 3 to 7 days.
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.

Dogs, cats:
20 – 50 mg benzylpenicillin procaine per kg body weight (bw) (corresponding to 11.7 – 29.1 mg benzylpenicillin per kg body weight)

corresponding to 1 – 2.5 ml of the veterinary medicinal product per 15 kg bw.
At least 3 treatments at 24 hour intervals.

Cattle, sheep, goats:
20 mg benzylpenicillin procaine per kg body weight (bw) (corresponding to 11.7 mg benzylpenicillin per kg body weight) corresponding to 1 ml of the veterinary medicinal product per 15 kg bw.
At least 3 treatments at 24 hour intervals.

Horses:
15 mg benzylpenicillin procaine per kg body weight (bw) (corresponding to 8.7 mg benzylpenicillin per kg bodyweight) corresponding to 0.75 ml of the veterinary medicinal product per 15 kg bw.
At least 3 treatments at 24 hour intervals.

Or
20 mg benzylpenicillin procaine per kg body weight (bw) (corresponding to 11.7 mg benzylpenicillin per kg body weight) corresponding to 1 ml of the veterinary medicinal product per 15 kg bw.
At least two treatments at 48 hour intervals.
Bacterial susceptibility should be tested.

Since repeated injections are required in a treatment cycle, varying injection sites should be used. The maximum application volume of the veterinary medicinal product per injection site is 20 ml.To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
Shake well before use.

The stopper can be safely punctured up to 20 times.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

10. WITHDRAWAL PERIOD(S)

Horse:
Meat and offal 10 days
Not authorised for use mares producing milk for human consumption.

Cattle, sheep and goat:
Meat and offal 10 days
Milk 120 hours (5 days)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after {EXP} the expiry date which is stated on the label.
Expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:

In competitive sport horses, it should be taken into account with regard to doping controls that the rapid dissociation of benzylpenicillin procaine may cause measurable procaine levels in urine and blood. Complete cross-resistance has been shown between Benzylpenicillin procaine and other penicillins. Use of the product should be carefully considered when antimicrobial susceptibility testing has shown resistance to penicillins because its effectiveness may be reduced.
After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the 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 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:
- *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;
- *S. aureus,* coagulase negative *Staphylococci* and *Enterococcus* spp. in dogs;
- *Staphylococcus aureus* and *Staphylococcus felis* in cats.
Use of the veterinary medicinal product may result in a lack of clinical efficacy when treating infections caused by these bacteria.

Special precautions for use in animals:
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other penicillins and 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 product if you know you are sensitised to penicillins or cephalosporins, or if you have been advised not to work with such preparations. Persons developing a reaction after contact with the product should avoid handling the product and other penicillin and cephalosporin containing products in future.

Handle this product with great care to avoid self-injection and exposure by accidental contact with the skin or eyes, taking all recommended precautions.

In case of accidental eye contact, rinse thoroughly with water. In case of accidental skin contact wash exposed skin thoroughly with soap and water.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
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:
Laboratory studies in animals have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use during pregnancy and lactation only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Natural penicillin is not compatible with metal ions, amino acids, ascorbic acid, heparin and vitamins of the B-complex. There is a potential antagonism of penicillin and chemotherapeutics regarding the bactericidal efficacy with a rapid onset of bacteriostatic effect. The excretion of benzylpenicillin is extended by probenecid, NSAIDs, sulfapyrazone and indomethacin. Inhibitors of the cholinesterase delay the degradation of procaine.

Overdose (symptoms, emergency procedures, antidotes):
In the case of overdosing central nervous excitations and convulsions may occur. The use of the product has to be terminated immediately and a symptomatic treatment (with benzodiazepines or barbiturates) should be initiated.

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

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon 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

15. OTHER INFORMATION

Pack Size:
100 ml