BOX

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procapen Injector 3g intramammary suspension for cattle
Benzylpenicillin, procaine monohydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each intramammary syringe:
Benzylpenicillin, procaine monohydrate 3.0 g
(equivalent to 1.7 g benzylpenicillin)

3. PHARMACEUTICAL FORM

Intramammary suspension *(already included in denomination)*

4. PACKAGE SIZE

24 intramammary syringes

5. TARGET SPECIES

Cattle (lactating cows)

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Shake thoroughly before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Meat and offal: 5 days
Milk: 6 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C-8°C)
Protect from light

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

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.

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

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4023

17. MANUFACTURER'S BATCH NUMBER

Batch

LABEL

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label Injector

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procapen Injector 3g intramammary suspension for cattle
Benzylpenicillin, procaine monohydrate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Benzylpenicillin, procaine monohydrate 3.0 g
(equivalent to 1.7 g benzylpenicillin)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Intramammary use *(already included in denomination)*
Shake

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: 5 days
Milk: 6 days

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

Procapen Injector 3g intramammary suspension for cattle

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:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procapen Injector 3g intramammary suspension for cattle

Benzylpenicillin, procaine monohydrate

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

Each 10 ml intramammary syringe contains a white to yellowish suspension:

Active substance:
Benzylpenicillin, procaine monohydrate 3.0 g
(equivalent to 1.7 g benzylpenicillin)

4. INDICATION(S)

For treatment of udder infection in lactating cows caused by benzylpenicillin-susceptible staphylococci and streptococci.

5. CONTRAINDICATIONS

Do not use in the case of:
- infections with β-lactamase-producing pathogens
- hypersensitivity to penicillins, other substances of the β-lactam group or to any of the excipients.

6. ADVERSE REACTIONS

Allergic reactions (anaphylactic shock, allergic skin reactions) are to be expected in animals which are sensitive to penicillin As the product contains polyvidone, rare cases of anaphylactic reaction may occur in cattle.
The animal should be treated symptomatically if an adverse reaction occurs.

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}.

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).

7. TARGET SPECIES

Cattle (lactating cows)

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

For intramammary use:
3.0 g benzylpenicillin, procaine monohydrate per diseased udder quarter, corresponding to: one syringe per diseased quarter every 24 h for 3 consecutive days.
If there is no clear improvement in the condition after 2 days of treatment, the diagnosis should be checked and the treatment changed, if appropriate.
A parenteral antibiotic is also to be administered in cases of mastitis with systemic symptoms.

9. ADVICE ON CORRECT ADMINISTRATION

All udder quarters are to be carefully milked immediately prior to each administration. After the teats and the teat tips have been cleaned and disinfected, one syringe is administered per udder quarter.
This product should be thoroughly shaken before use.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 5 days
Milk: 6 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C)
Protect from light
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and syringe after “EXP”. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Use of the 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 product is used.
Use of the product deviating from the instructions given in the package leaflet may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other beta lactam antimicrobials (penicillins and cephalosporins) due to the potential for cross-resistance.
The feeding of waste milk containing residues of penicillin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.
Care must be taken when applying the product in case of severe udder quarter swelling, milk duct swelling and/or congestion of detritus in the milk duct
Treatment should only be discontinued early after consultation with the veterinarian as this could lead to the development of resistant bacterial strains.

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.
- Handle this product with great care to avoid exposure by accidental contact with the skin or eyes. Persons developing a reaction after contact with the 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 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.
- Wash hands after use.

Pregnancy:
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
There is the possibility of antagonism towards antibiotics and chemotherapeutics with quick-onset bacteriostatic effect. The effect of aminoglycosides may be strengthened by penicillins.

Combinations with other medicines for intramammary use should be avoided because of possible incompatibilities.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
Not applicable.

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: Cardboard box containing 24 white linear low-density polyethylene intramammary syringes of 10 ml each.

Approved: 01 June 2018