

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procopen Injector 3g intramammary suspension

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

24 x 10 ml

4. TARGET SPECIES

Cattle (lactating cows)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Shake thoroughly before use.
Intramammary use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once the injector syringe is opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet 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

Distributor:

FORTE Healthcare Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 24745/5003

Vm 24745/3003

15. BATCH NUMBER

Lot {number

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Label Injector}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procopen Injector

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use immediately.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Procopen Injector 3g intramammary suspension for cattle

2. Composition

Each 10 ml intramammary syringe contains:

Active substance:

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

White to yellowish suspension.

3. Target species

Cattle (lactating cows)

4. Indications for use

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

5. Contraindications

Do not use in the cases of

- infections with β -lactamase-producing pathogens
- hypersensitivity to the active substance, other substances of the β -lactam group or to any of the excipients.

6. Special warnings

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 product is used.

Use of the veterinary medicinal 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 colostrum 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 veterinary medicinal 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 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 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.
- Wash hands after use.

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:

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 veterinary medicinal products for intramammary use should be avoided because of possible incompatibilities.

Major incompatibilities:

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

7. Adverse events

Cattle (lactating cows):

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|--|
| Rare (1 to 10 animals / 10,000 animals treated): |
| Anaphylactic reaction (severe allergic reaction) ¹ |
| Undetermined frequency (cannot be estimated from the available data): |
| Allergic reaction ² , anaphylactic shock ² , allergic skin reaction ² |

¹ due to the excipient polyvidone

² in animals which are sensitive to penicillin and/or procaine

The animal should be treated symptomatically if an adverse reaction occurs.

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 at <https://www.gov.uk/report-veterinary-medicine-problem>.

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

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 veterinary medicinal product should be thoroughly shaken before use

10. Withdrawal periods

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. Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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

Vm 24745/5003

Vm 24745/3003

Pack size: Cardboard box with 24 x 10 ml intramammary syringes.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

aniMedica GmbH

Im Südfeld 9

48308 Senden-Bösensell

Germany

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

Local representatives and contact details to report suspected adverse events:

FORTE Healthcare Limited,
Block 3, Unit 9,
CityNorth Business Campus,
Stamullen, Co.
Meath. K32 D990
Republic of Ireland
Tel.: +353 1 841 7666
E-Mail: pharmacovigilance@fortehealthcare.com

17. Other information

POM-V - Veterinary medicinal product subject to prescription

Gavin Hall

Approved 28 August 2025