

## **B. PACKAGE LEAFLET**

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### **Benzylpenicillin Vetcare 600 mg intramammary suspension for lactating cows**

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

Marketing authorisation holder: Vetcare Ltd, P.O. Box 99, 24101 Salo, Finland

Manufacturer for the batch release: aniMedica GmbH, Im Südfeld 9, 48308 Senden, Germany

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

Benzylpenicillin Vetcare 600 mg intramammary suspension for lactating cows

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

Each 10 g pre-filled syringe contains:

*Active substance:* Benzylpenicillin procaine 600 mg (600 000 IU)

*Other ingredients:* methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)

#### **4. INDICATION(S)**

Benzylpenicillin Vetcare is used for mastitis occurring during lactation phase and caused by penicillin-sensitive bacteria. Complementary to parenteral treatment with penicillin in clinical mastitis caused by invasive bacterial species, for instance *S. aureus*.

#### **5. CONTRAINDICATIONS**

Benzylpenicillin Vetcare should not be used to animals, which are hypersensitive to penicillin or procaine.

#### **6. ADVERSE REACTIONS**

If the animal is hypersensitive to penicillin or procaine, the undesirable effects may include oedema, dermatological changes and even an anaphylactic shock.

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

#### **7. TARGET SPECIES**

Cattle (lactating cow).

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

For intramammary use.

One syringe (10 g) of the product is given into an evacuated udder quarter once daily for 3-5 days. To achieve a higher drug concentration in the tissue, it is recommended to administer penicillin also via parenteral route at least in cases caused by invasive bacterial species, for instance *S. aureus*.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Clean the end of the teat carefully before applying the product. Remove the cover of the tip and infuse the product into the teat. The syringe has a double tip. In a normal case it is recommended to remove only the outer cover, revealing a tip about 5 mm long. Using the shorter tip reduces the mechanical irritation of the teat canal when the drug is applied. If the inner cover is removed as well, a tip of about 20 mm is revealed. This can be used to facilitate infusion, for instance to a teat with pronounced oedema. After infusion, the quarter is massaged so that the drug is evenly distributed. The quarter can be milked in 2-hour intervals.

## **10. WITHDRAWAL PERIOD**

Milk: 6 days. Edible tissues: 3 days.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use after the expiry date stated on the package.

## **12. SPECIAL WARNING(S)**

The efficacy of Benzylpenicillin Vetcare is reduced by simultaneous treatment with some antibiotics such as tetracycline or spiramycin.

Inappropriate use of the product may increase the prevalence of bacteria resistant to penicillin. Use of the product should take into account official and local antimicrobial policies. In some geographical areas or in some individual herds the resistance towards penicillin in *S. aureus* is widespread.

### **For the person administering the product:**

Wash your hands after the administration of the drug. Persons hypersensitive to penicillin or other betalactam antibiotics or procaine are advised to avoid skin contact with the drug. Benzylpenicillin may cause hypersensitivity reactions in skin contact and when ingested. These include rashes, oedema of larynx, lips or face, and shortness of breath. Contact your physician, if you get these symptoms while handling this medicinal product.

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

For environmental and safety reasons unused medicine should be submitted to pharmacy or to waste management.

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

30.6.2023

**15. OTHER INFORMATION**

Pack sizes: 3 x 10 g with 3 cleaning towels  
5 x 10 g with 5 cleaning towels  
100 x 10 g with 100 cleaning towels

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.