[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benzylpenicillin Vetcare 600 mg intramammary suspension for lactating cows.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 g pre-filled syringe contains:

Active substance:
Benzylpenicillin procaine 600 mg (600000 IU)

Excipient:
Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension for lactating cows.

Description of the product: white, oily suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (lactating cow).

4.2 Indications for use, specifying the target species

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.*

4.3 Contraindications

Hypersensitivity to penicillin or procaine.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash your hands after the administration of the drug. Persons hypersensitive to penicillin or other betalactam antibiotics 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 and face, and shortness of breath. Seek medical help, if you get these symptoms while handling the drug.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

The product is intended for use in mastitis occurring during lactation. The product can be used in pregnant cows.

4.8 Interaction with other medicinal products and other forms of interaction

The bactericidal action of penicillin is prevented by simultaneous treatment with bacteriostatic antibiotics such as tetracycline or spiramycin.

4.9 Amounts to be administered and administration route

One syringe of the product is given into an evacuated udder quarter once daily. 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*. The treatment is continued for 3-5 days.

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.

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

Not known.

4.11 Withdrawal period(s)

Milk: 6 days.
Edible tissues: 3 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-lactam antibacterials, penicillins, for intramammary use.
ATC vet code: QJ51CE09

5.1 Pharmacodynamic properties

Benzylpenicillin is a bactericidal antibiotic belonging to the betalactam group of antibiotics. It inhibits the peptidoglycan synthesis of Gram-positive bacteria. Benzylpenicillin has no effect on vegetative bacteria or on most of the Gram-negative bacteria.

Mastitis-causing streptococci are commonly sensitive to penicillin. Both *Staphylococcus aureus* and coagulase-negative staphylococci may synthesise betalactamase enzyme. These strains are resistant to penicillin. However, penicillin remains the drug of choice also for staphylococcal mastitis during

lactation, unless the pathogenic bacteria has been noted to be penicillin resistant in a sensitivity assay. Penicillin is effective on betalactamase-negative bacteria in much smaller concentrations than other antibiotics. The MIC values of penicillin to sensitive pathogens are ordinarily smaller than 0.15 μg/ml.

5.2 Pharmacokinetic particulars

Penicillin is minimally absorbed from the udder. Mammary oedema and exudate may inhibit the tissue distribution of the penicillin contained in the product. Thus sufficient drug concentrations might not be achieved. In healthy cows, one dose of Benzylpenicillin Vetcare intramammary is sufficient to maintain the drug concentration in milk above the MIC value (above 0.15 μg/ml) of those bacteria sensitive to penicillin for at least 24 h, even when the quarter is emptied at 2-h intervals.

Most of the penicillin in the product is excreted in milk unchanged. About 40% of the drug is eliminated in the milk at the first evacuation, and about 10% at the second evacuation. Therefore, about half of the penicillin dose has been eliminated after two milkings. Penicillin absorbed elsewhere in the organism is removed via kidneys in unchanged form.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Pionier MAA
Liquid paraffin
Lecithin (E322)

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

6.4. Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

White syringe of polyethylene with a double tip packed in a cardboard container.
Pack sizes: 3 x 10 g with 3 cleaning towels, 5 x 10 g with 5 cleaning towels and 100 x 10 g with 100 cleaning towels. Not all pack sizes may be marketed.

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

Vetcare Ltd, PO Box 99, 24101 Salo, Finland.

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2.4.2002

Date of last renewal: 2.9.2007

10 DATE OF REVISION OF THE TEXT

30.6.2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.