A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 3x10 g / 5x10 g / 20x10 g / 40x10 g / 100x10 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubropen 600 mg intramammary suspension for lactating cows

Benzylpenicillin procaine monohydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each 10 g intramammary syringe contains:
Benzylpenicillin procaine monohydrate 600 mg
(equivalent to 340.8 mg benzylpenicillin)

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

3 x 10 g with 3 cleaning towels
5 x 10 g with 5 cleaning towels
20 x 10 g with 20 cleaning towels
40 x 10 g with 40 cleaning towels
100 x 10 g with 100 cleaning towels

5. TARGET SPECIES

Cattle (lactating cow).

6. INDICATION(S)

-

7. METHOD AND ROUTE OF ADMINISTRATION

Intramammary use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:
Milk: 6 days.
Meat and offal: 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions.
See package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C.

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

Vetcare Oy
P.O. Box 99
24101 Salo
Finland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42810/4000

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 g syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubropen 600 mg intramammary suspension for lactating cows

Benzylpenicillin procaine monohydrate

2. QUANTITY OF THE ACTIVE SUBSTANCE

Benzylpenicillin procaine monohydrate 600 mg per syringe

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

10 g

4. ROUTE OF ADMINISTRATION

Intramammary use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Milk: 6 days.
Meat and offal: 3 days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Ubropen 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 Oy, P.O. Box 99, 24101 Salo, Finland

Manufacturer responsible for batch release:
aniMedica GmbH, Im Südfeld 9, 48308 Senden-Bösensell, Germany

or

KELA N.V., St. Lenaartseweg 48, B-2320 Hoogstraten, Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubropen 600 mg intramammary suspension for lactating cows

Benzylpenicillin procaine monohydrate

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

Each 10 g intramammary syringe contains:
Active substance:
Benzylpenicillin procaine monohydrate 600 mg (equivalent to 340.8 mg benzylpenicillin)

White to yellowish, oily suspension.

4. INDICATION(S)

Treatment of clinical mastitis caused by penicillin susceptible streptococci or staphylococci occurring during the lactation phase.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substances, to substances of the β-lactam group or to any of the excipients.
Do not use in cases of infections with β-lactamase-forming pathogens.

6. ADVERSE REACTIONS

Hypersensitive reactions to penicillin or procaine have been reported very rarely on post marketing safety experience and may include symptoms like oedema, dermatological changes such as urticaria, angio-oedema or erythema and anaphylactic shock.
In case adverse reactions occur, the current treatment should be withdrawn and symptomatic treatment should be initiated.
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

Cattle (lactating cow).

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

Intramammary use.
Infuse the contents of one intramammary syringe (equivalent to 600 mg benzylpenicillin procaine monohydrate) per affected udder quarter once daily after milking. The treatment is continued for 3-5 days.
Parenteral therapy may also be required depending upon the clinical presentation.

9. ADVICE ON CORRECT ADMINISTRATION

Clean and disinfect the end of the teat and teat orifice thoroughly before applying the product. Remove the cover of the tip and infuse the product gently into the teat. The intramammary syringe has a double tip. 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 veterinary medicinal product is applied (partial insertion). If the inner cover is removed as well, a tip of about 20 mm is revealed. This can be used only exceptionally to facilitate infusion, for instance to a teat with pronounced oedema (full insertion). The partial insertion technique is preferred, whenever achievable. After infusion, the quarter is massaged so that the drug is evenly distributed.

10. WITHDRAWAL PERIODS

Milk: 6 days.
Meat and offal: 3 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 25 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the intramammary syringe and carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
If the product is used in treatment of mastitis caused by *Staphylococcus aureus*, an appropriate parenteral antimicrobial may be required.

Special precautions for use in animals:
Use of the product should be based on identification and 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. In some geographical areas or in some individual herds resistance to penicillin in *S. aureus* is widespread.
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 antimicrobials to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select for antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

The cleaning towel should not be used in presence of teat injuries.

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.

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 penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

- Do not handle in case of hypersensitivity 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 taking all recommended precautions.
- Persons handling or administering the veterinary medicinal product should wear appropriate disposable gloves. Avoid contact with the eyes. Wash exposed skin after use. In case of eye contact, wash the eyes thoroughly with copious amounts of clean running water.
- If you develop symptoms following exposure such as a skin rash, you should seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

The cleaning towels provided contain isopropyl alcohol, which may be irritating to skin and eyes. It is recommended that disposable gloves are also worn when using the cleaning towels.
Wash hands after use.

Pregnancy and lactation:
Can be used during pregnancy, but not during the dry period.

Interaction with other medicinal products and other forms of interaction:
Do not combine with bacteriostatic agents. Tetracyclines, macrolides, sulphonamides, lincomycin or tiamulin may inhibit the antibacterial effect of penicillins because of the rapid onset of bacteriostatic action.

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

February 2021

15. OTHER INFORMATION

Pack sizes: 3 x 10 g with 3 cleaning towels,
5 x 10 g with 5 cleaning towels
20 x 10 g with 20 cleaning towels
40 x 10 g with 40 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.

Approved: 15/04/21