SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubrostar Red 100 mg / 280 mg / 100 mg, intramammary suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.5 g intramammary syringe contains:

Active substances:
Penethamate Hydriodide 100 mg (equivalent to 77.2 mg penethamate)
Benethamine Penicillin 280 mg (equivalent to 171.6 mg penicillin)
Framycetin Sulphate 100 mg (equivalent to 71.0 mg framycetin)

Excipients:

Qualitative composition of excipients and other constituents
Aluminium monostearate
Castor oil, hydrogenated
Liquid paraffin

White to off white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (Cows at drying off).

3.2 Indications for use for each target species

For treatment of subclinical mastitis at drying off, and the prevention of new bacterial infections of the udder during the dry period in dairy cows, caused by bacteria susceptible to penicillin and framycetin.

3.3 Contraindications

Do not use in lactating cows.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

Where there is a risk of summer mastitis, additional management procedures, such as fly control should be considered.

3.5 Special precautions for use

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 and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Serious acute mastitis [potentially lethal] due to pathogens like *Pseudomonas aeruginosa*, can occur after drying off despite preventive treatment. Good aseptic practices should be thoroughly respected in order to reduce that risk; cows should be housed in a hygienic paddock far from the milking parlour and regularly checked several days after drying off.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Skin sensitisation may occur in persons handling the veterinary medicinal product; care should be taken to avoid contact with skin.

Penicillins and cephalosporins may cause hypersensitivity 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.

1. Do not handle the veterinary medicinal product if you know that you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this veterinary medicinal product with care (especially persons with skin damage) to avoid exposure. Wear gloves, wash hands in case of contact with skin.

3. If you develop symptoms such as a skin rash following exposure, seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes, or difficulty breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle (Cows at drying off):

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national

competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation:
Do not use during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramammary use.
Intramammary administration of 100 mg penethamate hydriodide, 280 mg benethamine penicillin and 100 mg framycetin sulphate into each quarter, i.e. the contents of one syringe to be infused into each quarter immediately after the last milking of a lactation.
Before infusion, the udder should be milked out completely, the teats should be thoroughly cleaned and disinfected, and care should be taken to avoid contamination of the injector nozzle. Following infusion, it is advisable to use a teat wipe or spray.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No data available.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 10 days.

Milk: If treated at least 35 days before calving, milk must not be used for 36 hours after calving.
If treated less than 35 days before calving, milk must not be used for 37 days after treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ51RC25

4.2 Pharmacodynamics

Benethamine benzylpenicillin is the N-benzyl-2phenylethylamine salt of benzylpenicillin, designed as a long-acting formulation of benzylpenicillin. Penethamate is a prodrug from which benzylpenicillin and diethylaminoethanol are released by hydrolysis. Antimicrobial activity is derived exclusively from benzylpenicillin.

The free benzylpenicillin is effective chiefly against a variety of Gram-positive pathogens, excluding β-lactamase producing staphylococci. Penicillins act bactericidally on proliferating micro-organisms by inhibiting cell wall synthesis. The antibacterial activity is time dependent.

Framycetin, also known as neomycin B, is a bactericidal aminoglycoside antibiotic. Inhibition of bacterial protein synthesis and presumed interference with permeability at the cell membrane play a role in effecting bacterial cell death. Its action spectrum encompasses numerous Gram-negative and some Gram-positive bacteria.

In vitro efficacy of the combination of benzylpenicillin and framycetin has been demonstrated against: *Staphylococcus* spp*., Streptococcus* spp*., Arcanobacterium* spp. (*Corynebacterium* spp.), *Escherichia coli, Klebsiella* spp. and *Pseudomonas* spp*.*

4.3 Pharmacokinetics

The penicillin components of the veterinary medicinal product will remain in the dry udder for up to 3 weeks. In the majority of cows the framycetin components will remain in the dry udder for 10 weeks, or until calving.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Cardboard box or plastic container containing 20, 60 or 120 single use intramammary syringes and 20, 60 or 120 teat wipes (containing isopropanol 70%). Each 4.5 g syringe (cylinder with piston and cap, all made of low density polyethylene) contains 5 ml intramammary suspension.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd

7. MARKETING AUTHORISATION NUMBER

Vm 08327/3026

8. DATE OF FIRST AUTHORISATION

13 December 2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

May 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall
Approved: 10 December 2024