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:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension
White to off white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (at drying off).

4.2 Indications for use, specifying the 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.

4.3 Contraindications

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

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals
Use of the 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 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 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 product if you know that you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this 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 this warning to your doctor. Swelling of the face, lips or eyes, or difficulty breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation:
Do not use during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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 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.

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

No data available.

4.11 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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, Combination of antibacterials for intramammary use, Beta-lactam antibacterials, penicillins, combinations with other antibacterials.

ATCvet code: QJ51RC25.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

The penicillin components of the 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium monostearate
Castor oil, hydrogenated
Liquid paraffin

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 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.

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

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4307

9. DATE OF FIRST AUTHORISATION

13 December 2011

10. DATE OF REVISION OF THE TEXT

November 2018

Approved 09 November 2018