PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box (20 syringes) container (60 syringes) and container (120 syringes)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4.5 g intramammary syringe contains:
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)

3. PACKAGE SIZE

20 x 4.5 g (including 20 teat wipes)
60 x 4.5 g (including 60 teat wipes)
120 x 4.5 g (including 120 teat wipes)

4. TARGET SPECIES

Cattle (Cows at drying off).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramammary use.
Use the contents of one syringe per quarter after the last milking of a lactation.

7. WITHDRAWAL PERIODS

Withdrawal period:
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.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 08327/5059

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {SYRINGE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubrostar Red

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Penethamate hydriodide 100 mg, Benethamine penicillin 280 mg, Framycetin sulphate 100 mg.
4.5 g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

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

2. 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

3. Target species

Cattle (Cows at drying off).

4. Indications for use

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.

5. Contraindications

Do not use during lactation.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

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

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.

Pregnancy:
Can be used during pregnancy.

Lactation:
Do not use during lactation.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
No data available.

Major incompatibilities:
None known.

7. Adverse events

Cattle (Cows at drying off):

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Intramammary use.
The contents of one intramammary syringe (280 mg benethamine penicillin, 100 mg penethamate hydriodide and 100 mg framycetin sulphate) should be infused into each quarter immediately after the last milking of a lactation period.

9. Advice on correct administration

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 intramammary syringe.
Following infusion, it is advisable to use a teat wipe or spray.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the outer box and syringe after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 08327/5059

Carton box with 20 intramammary syringes x 4.5 g intramammary suspension
Container with 60 intramammary syringes x 4.5 g intramammary suspension
Container with 120 intramammary syringes x 4.5 g intramammary suspension

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK
Tel: +44 1344 746957

Manufacturer responsible for batch release:
Lohmann Pharmaherstellung GmbH
Heinz-Lohmann-Straße 5
27472 Cuxhaven
Germany

Haupt Pharma Latina S.r.l
S.S. 156 Monti Lepini Km 47,600
04100 Borgo San Michele - Latina
Italy

17. OTHER INFORMATION

Gavin Hall
Approved: 10 December 2024