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 for cattle
Penethamate Hydriodide / Benethamine Penicillin / Framycetin Sulphate

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. PHARMACEUTICAL FORM

Intramammary Suspension.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle (at drying off).

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Use the contents of one syringe per quarter after the last milking of a lactation.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4307

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubrostar Red 100 mg / 280 mg / 100 mg, Intramammary Suspension for cattle
Penethamate Hydriodide / Benethamine Penicillin / Framycetin Sulphate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

4.5 g

4. ROUTE(S) OF ADMINISTRATION

Intramammary use.

5. WITHDRAWAL PERIOD

Withdrawal periods:
Read the package leaflet before use.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

PACKAGE LEAFLET

Ubrostar Red 100 mg / 280 mg / 100 mg, Intramammary Suspension for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer responsible for the 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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubrostar Red 100 mg / 280 mg / 100 mg, Intramammary Suspension for cattle
Penethamate Hydriodide / Benethamine Penicillin / Framycetin Sulphate

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

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:
Aluminium monostearate
Castor oil, hydrogenated
Liquid paraffin

4. INDICATION(S)

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 case of hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

None known.
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.

7. TARGET SPECIES

Cattle (at drying off).

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

For 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.

10. WITHDRAWAL PERIOD(S)

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 35 or less 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 WARNING(S)

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

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.

Pregnancy:
Can be used during pregnancy.

Lactation:
Do not use during lactation.

Interactions:
None known.

Overdose:
No data available.

Incompatibilities:
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.

Pack size:
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.

Ubrostar Red 100 mg / 280 mg / 100 mg, Intramammary Suspension for cattle is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, used under licence.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 09 November 2018