PARTICULARS TO APPEAR ON THE OUTER PACKAGE: Carton, 20 injectors

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubro Red Dry Cow Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 5 ml injector contains:
Penethamate Hydriodide 100 mg
Procaine penicillin 300 mg
Framycetin sulphate 100 mg

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

20 Intramammary Injectors
Including Teat Wipes

5. TARGET SPECIES

Dry Cow

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramammary

8. WITHDRAWAL PERIOD

Withdrawal Periods: Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment. Milk for human consumption may only be taken from 84 hours (7 milkings) after calving. If calving occurs before 28 days after the last treatment, milk for human consumption may only be taken after 28 days plus 84 hours after the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Operator Warnings : 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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle the product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25˚C. Keep the syringe in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

The syringe must only be used once. Part used syringes must be discarded.
Disposal : Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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.

POM-V

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

Keep out of reach and sight 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 08327/4304

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

18. OTHER INFORMATION

Read the package leaflet before use.

To be used under veterinary supervision.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE: Bucket Label, 120 injectors

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubro Red Dry Cow Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 5 ml injector contains:

Penethamate Hydriodide	100 mg
Procaine penicillin	300 mg
Framycetin sulphate	100 mg

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

120 Intramammary Injectors
30 Cow Pack
Including Teat Wipes

5. TARGET SPECIES

Dry Cow

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramammary

8. WITHDRAWAL PERIOD

Not intended for use within 28 days of calving.
Withdrawal Periods : Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment. Milk for human consumption may only be taken from 84 hours (7 milkings) after calving. If calving occurs before 28 days after the last treatment, milk for human consumption may only be taken after 28 days plus 84 hours after the last treatment. Not to be used in the lactating cow.

9. SPECIAL WARNING(S), IF NECESSARY

Operator Warnings : 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.
1 Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2 Handle the product with great care to avoid exposure, taking all recommended precautions.
3 If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25˚C. Keep the syringe in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

The syringe must only be used once. Part used syringes must be discarded.
Disposal Advice : Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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.

POM-V

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

Keep out of reach and sight 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 08327/4304

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. OTHER INFORMATION

Read the package leaflet before use.

To be used under veterinary supervision.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS: 5 ml Injector

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubro Red Dry Cow Intramammary Suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 5 ml injector contains:

Penethamate Hydriodide	100 mg
Procaine penicillin	300 mg
Framycetin sulphate	100 mg

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

5 ml

4. ROUTE(S) OF ADMINISTRATION

Intramammary Suspension

5. WITHDRAWAL PERIOD

Withdrawal Periods :
Meat 28 days. Milk: 84 hours. If calving occurs before 28 days after the last treatment, milk for human consumption may only be taken after 28 days plus 84 hours after the last treatment.

6. BATCH NUMBER

Batch No.:

7. EXPIRY DATE

Expiry Date:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

9. OTHER INFORMATION

Contra indications, warnings : Do not use in the lactating cow or less than 28 days before calving. If a cow calves earlier than 28 days after treatment, consult your Veterinary Surgeon.

Penicillins/cephalosporins may occasionally cause severe allergic reactions. Read the package leaflet before use. See package leaflet for operator warnings/disposal advice.

Keep out of reach and sight of children. Do not store above 25°C. Keep the syringe in the outer carton. To be supplied only on veterinary prescription.

Vm 08327/4304

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

POM-V

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR: Ubro Red Dry Cow Intramammary Suspension

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

MA Holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer:
Lohmann Pharma Herstellung GmbH
27472 Cuxhaven, Germany.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubro Red® Dry Cow
Intramammary Suspension.

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

Composition
Each 5 ml Ubro Red® Dry Cow Intramammary injector contains:
Penethamate Hydriodide 100 mg
Procaine penicillin 300 mg
Framycetin sulphate 100 mg
Suspended in a white sterile slow-release ointment base.

Description
Ubro Red® Dry Cow contains a combination of an aminoglycoside, a penicillin ester and a penicillin salt, which gives a wide spectrum of antibacterial activity suspended in a slow-release base specifically designed for dry cow therapy.

4. INDICATION(S)

Indications
Routine dry cow therapy is established as an important part of mastitis control, in conjunction with teat dipping and other managemental factors. Ubro Red® Dry Cow is indicated for the treatment of sub-clinical infections present at drying off and to assist in preventing new infections occurring during the dry period. In the case of E coli infections this results in a reduction in the incidence of clinical mastitis during the first 100 days of the following lactation.

5. CONTRAINDICATIONS

Contra indications, warnings:
Not to be used in the lactating cow.
Not intended for use within 28 days of calving.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Dry Cow

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

Dosage and Administration: One injector per quarter at drying off.

9. ADVICE ON CORRECT ADMINISTRATION

Each quarter should be infused with the contents of one injector immediately after the last milking or lactation. Before infusing the teats should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle. Following infusion the teats should be dipped or sprayed with a teat disinfectant.

10. WITHDRAWAL PERIOD(S)

Withdrawal periods: Milk for human consumption may only be taken from 84 hours (7 milkings) after calving. Should a cow calve earlier than 28 days after treatment, consult your Veterinary Surgeon. If calving occurs before 28 days after the last treatment, milk for human consumption may only be taken after 28 days plus 84 hours after the last treatment. Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.
Producers should bear in mind their contractual obligations with their milk purchases, when retaining milk from newly calved cows.

11. SPECIAL STORAGE PRECAUTIONS

Storage
Do not store above 25°C. The syringe must be used once. Part used syringes must be discarded.

12. SPECIAL WARNING(S)

Operator warnings: 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.
1 Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2 Handle the product with great care to avoid exposure, taking all recommended precautions.

3 If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.

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

Disposal Advice : Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION>

Legal category POM-V
To be supplied only on veterinary prescription.

Presentation
Boxes of 20 injectors. Herd packs of 120 injectors. Packs contain medicated teatwipes.

Vm 08327/4304

Action
Following infusion, framycetin sulphate and the penicillin components are released slowly by the base and retained in the udder over a prolonged period.
Penethamate hydriodide has a similar range of activity as procaine penicillin and in-vitro, microorganisms sensitive to the procaine penicillin/penethamate hydriodide combination include streptococci, penicillin-sensitive staphylococci, *Arcanobacterium pyogenes, Corynebacteria bovis* and anaerobic micrococci. The penicillin component of Ubro Red® Dry Cow will remain above the M.I.C.s of these micro-organisms for up to 3 weeks in most dry udders. Micro-organisms, sensitive in-vitro to framycetin include penicillin resistant staphylococci, *E coli* and other Gramnegative bacteria. The framycetin component of Ubro Red® Dry Cow will remain above the m.i.c.s of these microorganisms for up to 14 weeks in most dry udders, though the effect of "bagging up" will reduce the concentration of framycetin to insignificant levels from a few days before calving**.**

For animal treatment only
Keep out of reach and sight of children.

Approved: 09 November 2018