PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton, 24 injectors

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubro Yellow Milking Cow Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 5 ml injector contains:
Framycetin Sulphate 100 mg
Penethamate Hydriodide 150 mg
Dihydrostreptomycin Sulphate 185 mg
(Equivalent to Dihydrostreptomycin 150 mg)
Prednisolone. 5 mg

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

24 Injectors

5. TARGET SPECIES

Milking Cow

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For dosage recommendations see package leaflet

8. WITHDRAWAL PERIOD

Milk for human consumption must not be taken from a cow during treatment. With cows milked twice daily, milk for human consumption may only be taken from 132 hours (i.e. at the 11th milking) after the last treatment. Where any other milking routine is followed, consult your Veterinary Surgeon. Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from 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 this 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.
4. Wash hands after use.
During a course of treatment, the situation should be reviewed frequently by close veterinary supervision.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Keep syringes in this carton.
Do not store above 25°C

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

The syringe must only be used once. Any unused product must be discarded.
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 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(S)

Vm 08327/4305

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. OTHER INFORMATION

Pack includes teat wipes

Cow Number or Name	Day, Date and Time of Treatments			Milk fit for Human Consumption
	Day/Date	Day/Date	Day/Date	Day/Date
	am	am	am	am
	pm	pm	pm	pm
	am	am	am	am
	pm	pm	pm	pm
	am	am	am	am
	pm	pm	pm	pm
	am	am	am	am
	pm	pm	pm	pm
	am	am	am	am
	pm	pm	pm	pm
	am	am	am	am
	pm	pm	pm	pm
	am	am	am	am
	pm	pm	pm	pm
	am	am	am	am
	pm	pm	pm	pm
	am	am	am	am
	pm	pm	pm	pm

Day and Time of last treatment		Milk fit for human consumption at:-		Day and Time of last treatment		Milk fit for human consumption at:-	
Monday	am	Saturday	pm	Friday	am	Wednesday	pm
	pm	Sunday	am		pm	Thursday	am
Tuesday	am	Sunday	pm	Saturday	am	Thursday	pm
	pm	Monday	am		pm	Friday	am
Wednesday	am	Monday	pm	Sunday	am	Friday	pm
	pm	Tuesday	am		pm	Saturday	am
Thursday	am	Tuesday	pm				
	pm	Wednesday	am				

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

5 ml INJECTOR

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubro YELLOW Milking Cow Intramammary Suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 5 ml injector contains:
Framycetin Sulphate 50 mg,
Penethamate Hydriodide 150 mg,
Dihydrostreptomycin Sulphate 185 mg, (Equivalent to Dihydrostreptomycin 150 mg) Prednisolone 5 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 and offal : 28 days
Milk : 132 hours/11 milkings

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 :Penicillin/ cephalosporins may occasionally cause severe allergic reactions. See package leaflet for further information.

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

VM 08327/4305

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:

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
D – 27472 Cuxhaven, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubro Yellow® Milking Cow
Intramammary Suspension.

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

Intramammary Suspension
Each 5ml Ubro Yellow® intramammary injector contains:
Penethamate Hydriodide 150 mg
Dihydrostreptomycin Sulphate 185 mg
(Equivalent to Dihydrostreptomycin 150 mg)
Framycetin Sulphate 50 mg
Prednisolone 5 mg
in an off-white sterile ointment base

4. INDICATION(S)

Uses
Ubro Yellow® contains a combination of antibiotics which give a wide spectrum of antibacterial activity for the treatment of bovine mastitis associated with penicillin, streptomycin and framycetin sensitive organisms. These include staphylococci (including penicillin resistant strains), streptococci (Str. agalactiae, Str.dysgalactiae and Str. Uberis), corynebacteria, Arcanobacterium pyogenes, E. Col, Klebsiella and Psuedomonas.

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

Milking Cow

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

Dosage and administration
Infuse one injector every 24 hours for three days, into the affected quarter after milking, using strict aseptic precautions.

9. ADVICE ON CORRECT ADMINISTRATION

Before infusion the teat should be thoroughly cleaned and disinfected and care taken to avoid contamination of the injector nozzle. Following infusion it is advisable to use a teat dip or spray. During a course of treatment, the situation should be reviewed frequently by close veterinary supervision.

10. WITHDRAWAL PERIOD(S)

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 must not be taken from a cow during treatment. With cows milked twice daily, milk may only be taken from 132 hours (i.e. at the 11th milking) after treatment. With other milking routines, the basis of the Veterinary Surgeon's advice should be that milk may be taken for human consumption only after the same period from the last treatment. For example, with three times a day milking, milk can be released for human consumption at the 16th milking after the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Pharmaceutical precautions
Do not store above 25°C. The syringe must be used once. Any unused product 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 crossreactions to cephalosporins and vice versa. Allergic reaction 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 this 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 may require urgent medical attention.
Wash hands after use.

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

Disposal
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

Date on which package leaflet was last prepared: May 2013

15. OTHER INFORMATION>

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

Package quantities
Boxes of 24 injectors.

Marketing Authorisation number:
Vm 08327/4305
For animal treatment only
Keep out of reach and sight of children.

Approved: 09 November 2018