PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ANOFLINE LACTATING COW INTRAMAMMARY SUSPENSION

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Anofline Lactating Cow Intramammary Suspension is an off-white to cream suspension supplying 200 mg amoxicillin (as amoxicillin trihydrate), 50 mg clavulanic acid (as potassium clavulanate) and 10mg prednisolone. per 3g syringe.

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

3g syringe

5. TARGET SPECIES

Lactating Cows

6. INDICATION(S)

Anofline Lactating Cow Intramammary Suspension is specially formulated for the treatment of bovine mastitis. It has a notably broad spectrum of bactericidal activity against the bacteria commonly found in the bovine udder. The prednisolone in Anofline Lactating Cow Intramammary Suspension has an anti-inflammatory action which helps to reduce the potentially destructive swelling and inflammation associated with mastitis, without affecting the white cell response to infection.

In vitro, Anofline Lactating Cow Intramammary Suspension is active against a wide range of clinically important bacteria, including the following organisms, which are commonly associated with bovine mastitis:

Staphylococci (including beta-lactamase producing strains).

Streptococci (including *S. agalactiae, S. dysgalactiae* and *S. uberis*).

A. pyogenes and other minor members of the *Corynebacteria* spp.

Escherichia coli (including beta-lactamase producing strains).

In addition, it is active *in vitro* against many less common udder pathogens including:

Bacillus cereus, Bacteroides (including beta-lactamase producing strains), *Campylobacter* spp., *Klebsiellae* and *Pasteurellae.*

Clinically, Anofline Lactating Cow Intramammary Suspension has been shown to be an effective, routine treatment for mastitis in lactating cows. Cases responding successfully to treatment include infections with the following major pathogens:

Staphylococci (including beta-lactamase producing strains).

Streptococci (including *S. agalactiae, S. dysgalactiae* and *S. uberis*).

Escherichia coli (including beta-lactamase producing strains)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Anofline Lactating Cow Intramammary Suspension should be administered at a dose rate of 3 syringes per infected quarter with a single syringe given every 12 hours. Use each syringe only once.

After milking, clean and disinfect the teat end thoroughly with surgical spirit. Insert the syringe nozzle into the teat orifice and apply gentle and continuous pressure until the entire suspension is released. The treated quarter(s) may be milked out at the next normal milking time, but the milk should be discarded.

8. WITHDRAWAL PERIOD

Cattle: (meat & offal): 7 days

(milk): 84 hours

9. SPECIAL WARNING(S), IF NECESSARY

Anofline Lactating Cow Intramamary Suspension is contra-indicated in known cases of hypersensitivity to penicillins.

Operator Warnings - Penicillin/Cephalosporin Sensitivity:

When infusing heifers, protective gloves should always be worn in order to avoid skin contact.

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.

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

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

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Syringes are for single use only. Discard after use.

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

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

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MANUFACTURED BY:

Norbrook Laboratories Limited

Station Works

Newry

Co. Down, BT35 6JP

DISTRIBUTED BY:

Norbrook Laboratories (GB) Limited

1 Saxon Way East

Oakley Hay Industrial Estate

Corby

Northamptonshire

NN18 9EX

United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4199

ManA 2000

17. MANUFACTURER'S BATCH NUMBER

BN.:

D.O.M.: dd/mm/yy

PACKAGE QUANTITIES:

Supplied in a low-density polyethylene syringe with cap, delivering 3 g of product, in 12 or 24 syringes.

FURTHER INFORMATION:

Resistance to many antibiotics is caused by bacterial beta-lactamase enzymes which destroy the antibiotic before it can act. The clavulanic acid in Anofline Lactating Cow Intramammary Suspension counteracts this defence mechanism by inactivating the beta-lactamases, thus rendering the bacteria sensitive to amoxicillin's rapid bactericidal effect, at concentrations readily attainable in the udder.

Anofline Lactating Cow Intramammary Suspension is effective against *Klebsiella* infections found in veterinary practice, but it is not indicated for cases involving Pseudomonas species.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ANOFLINE LACTATING COW INTRAMAMMARY SUSPENSION

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each syringe nominally contains 200 mg amoxicillin as amoxicillin trihydrate, 50 mg clavulanic acid as potassium clavulanate and 10 mg prednisolone in an oily base.

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

3g

4. ROUTE(S) OF ADMINISTRATION

For intramammary administration to lactating cattle at a dose rate of 3 syringes per affected quarter with one syringe administered every 12 hours.

5. WITHDRAWAL PERIOD

Meat: 7 days. Milk: 84 hours

6. BATCH NUMBER

BN.:

D.O.M.:

7. EXPIRY DATE

EXP.:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Contraindications and Warnings:

Syringes are for single use only.

Discard after use.

Do not store above 25°C. Store out of reach of children.

See carton label for operator warnings.

Further Information:

Refer to Packaging Text

ManA 2000

Vm: 02000/4199

Manufactured by:

Norbrook Laboratories Limited

Station Works

Newry
Co. Down, BT35 6JP

Distributed by:

Norbrook Laboratories (GB) Limited

1 Saxon Way East

Oakley Hay Industrial Estate

Corby

Northamptonshire

NN18 9EX

United Kingdom

POM-V

To be supplied only on veterinary prescription.

PACKAGE LEAFLET FOR:

ANOFLINE LACTATING COW INTRAMAMMARY SUSPENSION

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

Norbrook Laboratories Limited

Station Works

Newry

Co. Down, BT35 6JP

Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ANOFLINE LACTATING COW INTRAMAMMARY SUSPENSION

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

Anofline Lactating Cow Intramammary Suspension is an off-white to cream suspension supplying 200 mg amoxicillin (as amoxicillin trihydrate), 50 mg clavulanic acid (as potassium clavulanate) and 10mg prednisolone per 3g syringe.

4. INDICATION(S)

Anofline Lactating Cow Intramammary Suspension is specially formulated for the treatment of bovine mastitis. It has a notably broad spectrum of bactericidal activity against the bacteria commonly found in the bovine udder. The prednisolone in Anofline Lactating Cow Intramammary Suspension has an anti-inflammatory action which helps to reduce the potentially destructive swelling and inflammation associated with mastitis, without affecting the white cell response to infection.

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A. pyogenes and other minor members of the *Corynebacteria* spp.

Escherichia coli (including beta-lactamase producing strains).

In addition, it is active *in vitro* against many less common udder pathogens including:

Bacillus cereus, Bacteroides (including beta-lactamase producing strains), *Campylobacter* spp., *Klebsiellae* and *Pasteurellae.*

Clinically, Anofline Lactating Cow Intramammary Suspension has been shown to be an effective, routine treatment for mastitis in lactating cows. Cases responding successfully to treatment include infections with the following major pathogens:

Staphylococci (including beta-lactamase producing strains).

Streptococci (including *S. agalactiae, S. dysgalactiae* and *S. uberis*).

Escherichia coli (including beta-lactamase producing strains).

5. CONTRAINDICATIONS

During the course of treatment the situation should be reviewed frequently by close veterinary supervision.

Anofline Lactating Cow Intramammary Suspension is contra-indicated in known cases of hypersensitity to penicillins.

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Lactating Cow

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

Anofline Lactating Cow Intramammary Suspension should be administered at a dose rate of 3 syringes per infected quarter with a single syringe given every 12 hours. Use each syringe only once.

9. ADVICE ON CORRECT ADMINISTRATION

After milking, clean and disinfect the teat end thoroughly with surgical spirit. Insert the syringe nozzle into the teat orifice and apply gentle and continuous pressure until the entire suspension is released. The treated quarter(s) may be milked out at the next normal milking time, but the milk should be discarded.

10. WITHDRAWAL PERIOD(S)

Cattle: (meat & offal): 7 days

(milk): 84 hours

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Syringes are for single use only. Discard after use.

12. SPECIAL WARNING(S)

Operator Warnings - Penicillin/Cephalosporin Sensitivity:

When infusing heifers, protective gloves should always be worn in order to avoid skin contact.

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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

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

July 2019

15. OTHER INFORMATION

POM-V

To be supplied only on Veterinary prescription.

PACKAGE QUANTITIES:

Supplied in a low-density polyethylene syringe with cap, delivering 3 g of product. in cartons containing 12 or 24 Syringes.

Not all pack sizes may be marketed.

FURTHER INFORMATION:

Resistance to many antibiotics is caused by bacterial beta-lactamase enzymes which destroy the antibiotic before it can act. The clavulanic acid in Anofline Lactating Cow Intramammary Suspension counteracts this defence mechanism by inactivating the beta-lactamases, thus rendering the bacteria sensitive to amoxicillin's rapid bactericidal effect, at concentrations readily attainable in the udder.

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Approved 08 August 2019