LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ampredclav Intramammary Suspension for Lactating Cows

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

Cattle: Meat: 7 days.

Milk: 84 hours

6. BATCH NUMBER

B.N.:

7. EXPIRY DATE

D.O.M.:

Exp.: dd/mm/yy

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only

POM-V

To be supplied only on veterinary prescription

Futher Information:

Contraindications and Warnings:

Syringes are for single use only. Do not store above 25°C. Store out of reach of children. See carton label for operator warnings. Keep container in outer carton.

Man 2000
Vm: 02000/4240

Manufactured by:
Norbrook Laboratories Limited
Station Works, Newry
Co. Down, BT35 6JP

Distributed by:
Norbrook Laboratories (GB) Limited
The Green, Great Corby
Carlisle, CA4 8LR

DRAFT CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ampredclav Intramammary Suspension for Lactating Cows

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Intramammary suspension, Lactating cow

4. PACKAGE SIZE

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

5. TARGET SPECIES

Lactating Cattle

6. INDICATION(S)

Ampredclav Intramammary Suspension for Lactating Cows 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 Ampredclav Intramammary Suspension for Lactating Cows 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, Ampredclav Intramammary Suspension for Lactating Cows 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, Ampredclav Intramammary Suspension for Lactating Cows 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).

Official national and regional antimicrobial policies should be taken into account when the product is used.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Ampredclav Intramammary Suspension for Lactating Cows 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.
Combined Therapy for the treatment of bovine mastitis. In the situation where systemic treatment as well as intramammary treatment is necessary, Combiclav Injection can be administered in combination with Combiclav Lactating Cow Intramammary Suspension using the following minimum treatment regime:

Combiclav Injection	Ampredclav Intramammary
8.75 mg/kg bodyweight (7.0 mg amoxicillin, 1.75 mg clavulanic acid) i.e. 1 ml/20 kg bodyweight. 24 hours ↓ 8.75 mg/kg bodyweight (7.0 mg amoxicillin, 1.75 mg clavulanic acid) i.e. 1 ml/20 kg bodyweight. 24 hours ↓ 8.75 mg/kg bodyweight (7.0 mg amoxicillin, 1.75 mg clavulanic acid) i.e. 1 ml/20 kg bodyweight. Where necessary Combiclav Injection may be administered for an additional two days for a total of 5 daily injections.	One syringe gently infused into the teat of the infected quarter 12 hours ↓ One syringe gently infused into the teat of the infected quarter 12 hours ↓ One syringe gently infused into the teat of the infected quarter

8. WITHDRAWAL PERIOD

Cattle (meat & offal): 7 days
(milk): 84 hours

Combined Therapy: When using Ampredclav Intramammary Suspension for Lactating Cows and Combiclav Injection in combination: Meat and Offal: 42 days, Milk: 84 hours from last treatment of Combiclav Injection following the minimum posology regime as described under dosage for each species, routes and method of administration.

9. SPECIAL WARNING(S), IF NECESSARY

Operator Warnings- Penicillin/Cephalosporin Sensitivity
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.

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

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.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Syringes are for single use only. Keep container in outer carton.

12. SPECIAL 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

Package Quantities:
Supplied in a low-density polyethylene syringe with cap, delivering 3 g of product.

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 Ampredclav Intramammary Suspension for Lactating Cows 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.

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

Distributed By:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

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

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4240

17. MANUFACTURER'S BATCH NUMBER

BN.:
D.O.M:

DRAFT INSERT TEXT

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
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ampredclav Intramammary Suspension for Lactating Cows

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

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

4. INDICATION(S)

Ampredclav Intramammary Suspension for Lactating Cows 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 Ampredclav Intramammary Suspension for Lactating Cows 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, Ampredclav Intramammary Suspension for Lactating Cows is active against a wide range of clinically important bacteria, including the following organisms, which are commonly associated with bovine mastitis:

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

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Official national and regional antimicrobial policies should be taken into account when the product is used.

5. CONTRAINDICATIONS

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.

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 Cattle

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

Combined Therapy for the treatment of bovine mastitis. In the situation where systemic treatment as well as intramammary treatment is necessary, Combiclav Injection can be administered in combination with

Ampredclav Intramammary Suspension for Lactating Cows using the following minimum treatment regime:

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9. ADVICE ON CORRECT ADMINISTRATION

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10. WITHDRAWAL PERIOD

Cattle (meat & offal): 7 days
(milk): 84 hours

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11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Keep out of the reach and sight of children. Syringes are for single use only. Keep container in outer carton.

12. SPECIAL WARNINGS

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.

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 2020

15. OTHER INFORMATION

Resistance to many antibiotics is caused by bacterial beta-lactamase enzymes which destroy the antibiotic before it can act. The clavulanic acid in Ampredclav Intramammary Suspension for Lactating Cows 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.
Ampredclav Intramammary Suspension for Lactating Cows is effective against *Klebsiella* infections found in veterinary practice, but it is not indicated for cases involving Pseudomonas species.

DISTRIBUTED BY:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

Package Quantities:
Supplied in a low-density polyethylene syringe with cap, delivering 3 g of product. Available in cartons of 24 syringes.

For Animal Treatment only
UK Authorised Veterinary Medicinal Product

POM-V

To be supplied only on veterinary prescription

B.N.:
D.O.M.:
Exp.:

Vm: 02000/4240
ManA 2000

Approved 01 July 2020