SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ampredclav Intramammary Suspension for Lactating Cows

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each 3g syringe supplies:

Active Ingredients:

Amoxicillin (as amoxicillin trihydrate)	200 mg
Clavulanic acid (as potassium clavulanate)	50 mg
Prednisolone	10 mg

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Intramammary suspension
An off white to cream suspension.

4. CLINICAL PARTICULARS

4.1 Target species:

Lactating cattle.

4.2 Indications for use, specifying the target species:

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 isolated from 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.

(i) *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*.

(ii) 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).

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.

4.3 Contraindications:

Ampredclav Intramammary Suspension for Lactating Cows is contraindicated in known cases of hypersensitivity to penicillins.

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

4.4 Special Warnings for each target species:

None.

4.5 Special precautions for use:

Special precautions for use in animals:

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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.

4.6 Adverse reactions (frequency and seriousness):

None known.

4.7 Use during pregnancy, lactation or lay:

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction:

None known.

4.9 Amounts to be administered and administration route:

Ampredclav Intramammary Suspension for Lactating Cows is suitable for intramammary administration to lactating cattle at a dose rate of 3 syringes per affected quarter administered singly at 12 hour intervals. 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 suspension is expressed. The treated quarter(s) may be milked out at the next normal milking time, but the milk should be discarded.

For Combined therapy the following minimum treatment regime should be followed:

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary:

Not applicable.

4.11 Withdrawal period:

Meat & Offal: 7 days
Milk: 84 hours

Combined Therapy:

When using Ampredclav Intramammary Suspension for Lactating Cows and Combiclav Injection in combination:
Meat & Offal: 42 days
Milk: 84 hours
from the last treatment of Combiclav Injection, following the minimum posology regime as described in Section 4.9

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial and Corticosteriods

ATC Vet Code: QJ51RV01

5.1 Pharmacodynamic properties:

Amoxicillin is a beta-lactam antibiotic and its structure contains the beta-lactam ring and thiazolidine ring common to all penicillins. Amoxicillin shows excellent activity against susceptible Gram-positive bacteria and Gram-negative bacteria.

Beta-lactam antibiotics prevent the bacterial cell wall from forming by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes, which catalyse cross-linkage of the glycopeptide polymer units that form the cell wall. They exert a bactericidal action but cause lysis of growing cells only.

Clavulanic acid is one of the naturally occurring metabolites of the streptomycete *Streptomyces clavuligerus.* It has a structural similarity to the penicillin nucleus, including possession of a beta-lactam ring. Clavulanic acid is a beta-lactamase inhibitor acting initially competitively but ultimately irreversibly. Clavulanic acid will penetrate the bacterial cell wall binding to both extracellular and intracellular beta-lactamases.

Amoxicillin is susceptible to breakdown by β-lactamase and therefore combination with an effective ß-lactamase inhibitor (clavulanic acid) extends the range of bacteria against which it is active to include β-lactamase producing species.

Prednisolone is a corticosteroid of the glucocorticoid class. Prednisolone has significant anti-inflammatory properties. This anti-inflammatory action helps to reduce the swelling and inflammation associated with mastitis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Silicon Dioxide Precipitated.
Paraffin Light Liquid.
Paraffin White Soft.

6.2 Major incompatibilities:

None Known.

6.3 Shelf life:

Shelf life of the veterinary medicinal product as packaged for sale: 1 Year

6.4 Special precautions for storage:

Do not store above 25°C.
Syringes are for single use only.

6.5 Nature and composition of immediate packaging:

A low-density polyethylene syringe with cap, delivering 3 g of product.
Available in cartons of 24 syringes.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4240

9. DATE OF FIRST AUTHORISATION

18 September 2003

10. DATE OF REVISION OF THE TEXT

July 2020

Approved 01 July 2020