SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combiclav Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance(s)	mg/ml
Amoxicillin (as Amoxicillin trihydrate)	140
Clavulanic acid (as Potassium clavulanate)	35

Excipients:	
Butylated Hydroxyanisole	0.08
Butylated Hydroxytoluene	0.08

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
An off-white to cream oily suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

Combiclav Injection has a broad spectrum of bactericidal activity against the bacteria commonly found in cattle.

(a) *In vitro* Combiclav Injection is active against a wide range of clinically important bacteria including:

Gram-positive: Staphylococci (including beta-lactamase producing strains), Streptococci, Corynebacteria, Clostridia, *Bacillus anthracis*, *Actinomyces bovis*.

Gram-negative: *Escherichia coli* (including beta-lactamase producing strains), *Salmonella* spp (including beta-lactamase producing strains), *Campylobacter* spp,

Klebsiella spp, *Proteus* spp, *Pasteurella* spp, *Fusobacterium necrophorum*, Bacteroides (including beta-lactamase producing strains), *Haemophilus* spp, *Moraxella* spp and *Actinobacillus lignieresi.*

(b) Treats:

Cattle:

Respiratory infections
Soft tissue infections (e.g. joint/navel ill, abscesses etc.)
Metritis
Mastitis.
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.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

The product should not be administered to rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in other very small herbivores.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

Official and local antimicrobial policies should be taken into account when the product is used.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

Avoid use of the product in herds where no β-lactamase producing *Staphylococci* strains have been isolated. Veterinarians should strive to use narrow spectrum antibiotics if possible.
Inappropriate use of the product may increase the prevalence of bacteria resistant to ß-lactam antibiotics and may decrease the effectiveness of treatment with ß-lactam antibiotics, due to the potential for cross-resistance.

Care should be taken to avoid contaminating the remaining contents of a vial with water.

Clavulanic acid is moisture sensitive. It is very important therefore, that a completely dry needle and syringe is used when extracting suspension for injection in order to avoid contaminating the remaining contents of the vial with drops of water.
Contamination will result in obvious beads of dark, brown discolouration corresponding to the introduced water droplets. Material affected in this way should not be used as it may have significantly reduced potency.

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

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.
Care should be taken to avoid accidental self-injection.
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 in breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Use of the product may occasionally result in pain on injection and/or local tissue reaction.

Allergic reactions (allergic skin reactions, anaphylaxis) may occasionally occur. If allergic reactions occur, the product should be discontinued immediately. Appropriate symptomatic treatment should be initiated.

4.7 Use during pregnancy, lactation or lay

The product may be used safely in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

For intramuscular injection at a dosage rate of 8.75 mg/kg bodyweight (1 ml per 20 kg bodyweight) daily for 3-5 days. Shake the vial well before use. After injection, massage the injection site. Use a completely dry sterile needle and syringe. Swab the septum before removing each dose.

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

Combiclav Injection	**Combiclav LC 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

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

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

Potentiated penicillin is of a low order of toxicity and is well tolerated by the parenteral route. Apart from occasional injection site reactions, which may occur at the recommended dose, no other adverse effects are to be expected from an accidental overdose.

4.11 Withdrawal period(s)

Meat and offal: 42 days.
Milk: 60 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Amoxicillin and enzyme inhibitor

ATC Vet Code: QJ01CR02

5.1 Pharmacodynamic properties

Mode of Action

Amoxicillin:

The mechanism by which ß-lactam antibiotics bind with proteins associated with developing the bacterial cell wall, resulting in the ultimate lysis of the cell, is well established. In the case of Gram-positive bacteria the ß-lactam can freely pass across the peptidoglycan layer in the aqueous phase to the site of activity at the cytoplasmic membrane. In the case of Gram-negative bacteria there is a hydrophobic barrier outside the peptidoglycan layer. Broad-spectrum ß-lactam antibiotics have the ability to cross this barrier by way of small pores in its structure.

There are three major mechanisms of resistance available to bacteria: the production of ß-lactamase enzymes, impermeability of the cell wall by modification of the small pores and by modifications of the amino acid sequences at the cytoplasmic membrane interface where the cell wall is constructed.

Clavulanic Acid:

In the absence of specific inhibitor enzymes with ß-lactamase activity, ß-lactamases either form complexes with the antibiotic or cause a breakdown of the ß-lactam ring. In either case the antibacterial activity is lost.

Clavulanic acid has a ß-lactam ring in its structure which is recognised by ß-lactamases as a type of “penicillin”. The enzyme/clavulanate interaction is irreversible and results in the depletion of enzymes molecules.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated Hydroxyanisole
Butylated Hydroxytoluene
Propylene Glycol Octanoate Decanoate

6.2 Major Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25ºC.
Keep container in outer carton

Discard unused material.

This product does not contain an antimicrobial preservative.
Once a vial has been broached the contents should be used within 28 days.

6.5 Nature and composition of immediate packaging

50 and 100 ml siliconised, clear, colourless, glass (Type II) vials with nitryl bung secured with aluminium overseal.

Not all pack sizes may be marketed.

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
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4238

9. DATE OF FIRST AUTHORISATION

24 September 2003

10. DATE OF REVISION OF THE TEXT

May 2026

Gavin Hall
Approved: 19 May 2026