Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav Injection for Cattle and Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Amoxycillin (as Amoxycillin trihydrate) 14.0% w/v
Clavulanic acid (as Potassium clavulanate) 3.5% w/v

Excipients:
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

A suspension for injection.

An off-white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Dogs.

4.2 Indications for use, specifying the target species

Noroclav Injection has a broad-spectrum of bactericidal activity against the bacteria commonly found in cattle and dogs.

(a) *In vitro* Noroclav 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, *Pasteurellae* spp, *Fusobacteriumnecrophorum*, Bacteroides (including beta-lactamase producing strains), *Haemophilus* spp, *Moraxella* spp and *Actinobacillus lignieresi*.

(b) Noroclav Injection is indicated for the treatment of diseases including:

Cattle:

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

Dogs:

Respiratory tract infections
Urinary tract infections
Skin and soft tissue infections (e.g. abscesses, pyoderma, anal sacculitis and gingivitis.)

4.3 Contraindications

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

Special precautions for use in animals
Do not use in animals with known hypersensitivity to penicillin or other substances of the beta-lactam group.

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.
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)

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

4.7 Use during pregnancy, lactation or lay

The product may be used safely in pregnant animals, subject to observance of the withholding time for milk and the withdrawal time for meat intended for human consumption.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

The product is indicated for intramuscular administration to cattle and subcutaneous administration to dogs.

The recommended dosage rate is 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. This product does not contain an antimicrobial preservative. Use a completely dry sterile needle and syringe. Swab the septum before removing each dose.

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.

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)

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 42 days from the last treatment.

Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from treated cattle only after 80hours from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-infective for systemic use: amoxicillin and enzyme inhibitor.

ATC Vet Code: QJ01CR02

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 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 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 ß-lactamases produced by some bacterial species, and therefore combination with an effective ß-lactamase inhibitor (clavulanic acid) extends the range of bacteria against which it is active to include ß-lactamase producing species.

5.2 Pharmacokinetic particulars

After parenteral administration of the maximum recommended dose to cattle, the following parameters were observed: Cmax of 1.69 µg/ml, Tmax of 2.67h, AUC of

30.59 µg/ml.h and t½ of 23.19h foramoxicillin and Cmax of 0.94 µg/ml, Tmax of 1.3h, AUC of 3.123 µg/ml.h and t½ of 1.71h for clavulanic acid.

After subcutaneous administration of the maximum recommended dose to dogs, the following parameters were observed: Cmax of 8.66 µg/ml, Tmax of 1.78h and AUC of 50.98 µg/ml.h foramoxicillin

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated Hydroxyanisole
Butylated Hydroxytoluene
Propylene Glycol Dicaprylate/Dicaprate

6.2 Major incompatibilities

None known.

6.3 Shelf-life

1 year.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

Noroclav Injection will be supplied in clear colourless type II glass vials of 50 ml and 100 ml, complete with nitryl bungs and aluminium caps.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/058/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 September 2002
Date of last renewal: 26 September 2007

10 DATE OF REVISION OF THE TEXT

December 2018