Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Ready to Use Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances
Amoxicillin (as amoxicillin trihydrate) 140mg
Clavulanic acid (as potassium clavulanate) 35mg
For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

An off-white to pale buff coloured smooth, fluid, readily dispersible suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs, dogs and cats.

4.2 Indications for use, specifying the target species

This product has bactericidal activity against a broad spectrum of clinically important bacteria found in large and small animals. *In vitro* the product is active against a wide range of bacteria, including strains resistant to Amoxicillin alone because of beta-lactamase production:

Gram-positive
Actinomyces bovis
Bacillus anthracis
Clostridia
Corynebacteria
Peptostreptococcus spp.
Staphylococci (including β-lactamase producing strains)
Streptococci

Gram-negative
Actinobacillus lignierisi
Actinobacillus pleuropneumoniae
Bacteroides (including β-lactamase producing strains)
Bordetella bronchiseptica
Campylobacter spp.
Escherichia coli (including β-lactamase producing strains)
Fusobacterium necrophorum
Haemophilus spp.
Klebsiellae
Moraxella spp.
Pasteurellae
Proteus spp.
Salmonellae (including β-lactamase producing strains)

Clinically the product is indicated for the treatment of diseases including:

Cattle:

Respiratory infections, soft tissue infections (e.g joint-ill/navel-ill, abscesses etc.), metritis and mastitis.

Pigs;
Respiratory bacterial infections in growing pigs; Colibacillosis, Periparturient infections in sows (e.g. mastitis, metritis and agalactia.)

Dogs and Cats;
Respiratory tract infections, urinary tract infections and skin and soft tissue infections (e.g. abscesses, pyoderma, anal sacculitis, 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.

Do not use in animals known to be hypersensitive to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Care should be taken to avoid contaminating the remaining contents of a vial with water. Clavulanic acid is moisture sensitive. It is very important that a completely dry syringe is used when extracting the 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.

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.

4.6 Adverse reactions (frequency and seriousness)

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

By either intramuscular or subcutaneous injection at a dosage rate of 8.75 mg/kg bodyweight (1 ml / 20 kg bodyweight) daily for 3-5 days.

Shake the vial well before use. After injection, massage the injection site.Use a completely dry needle and syringe. Swab the septum before removing each dose.

Combined therapy for the treatment of bovine mastitis:
In the situation where systemic treatment as well as intramammary treatment is necessary, Synulox Ready-to-Use Injection can be used in combination with Synulox Lactating Cow Intramammary.

For combined therapy, the following minimum treatment regime should be followed:

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

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

Synulox 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 expected from an accidental overdose.

4.11 Withdrawal period(s)

Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken only from cattle from 80 hours after the last treatment. 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, and pigs after 31 days.

Combined therapy: When using Synulox RTU and Synulox LC Intramammary in combination, animals must not be slaughtered for human consumption during treatment. Cows may not be slaughtered for human consumption until 42 days after the last treatment. Milk must not be taken for human consumption during treatment. Milk for human consumption may be taken only from cows after 80 hours from the last treatment of Synulox RTU following the minimum posology regime as described in Section 4.9.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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 the 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 modification 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 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-lactamase as a type of “penicillin”. The enzymes/clavulanate interaction is irreversible and results in the depletion of enzyme molecules.

5.2 Pharmacokinetic particulars

Following either subcutaneous or intramuscular administration of Synulox RTU to dogs and cats, and intramuscular administration to cattle and pigs, both amoxicillin and clavulanic acid are well absorbed and well distributed in the tissues. The major route of elimination of amoxicillin and clavulanic acid is via the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Fractionated coconut oil

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place.

6.5 Nature and composition of immediate packaging

Type III glass vials of 40 ml containing an off-white sterile, non-aqueous suspension. The vials are sealed with a rubber bung and an aluminium seal and packed in cardboard containers, 12 x 40ml. Each glass vial contains a sterile off-white to pale buff coloured, smooth fluid, readily dispersable suspension.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

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Cherrywood Business Park, Loughlinstown
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