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SYNULOX Ready-To-Use Suspension for Injection

Species: Cats, Cattle, Dogs, Pigs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Injections

Active ingredient: Amoxicillin Trihydrate, Clavulanic Acid

Product: Synulox® RTU

Product index: Synulox RTU

Cattle - milk:60 hours

Cattle - meat:42 days

Pig - meat:31 days

Incorporating:

Qualitative and quantitative composition

Each 1 ml contains:

Active ingredients:

Amoxicillin (as amoxicillin trihydrate)

Clavulanic acid (as potassium clavulanate)

For the full list of all other excipients see section "Pharmaceutical particulars".

Pharmaceutical form

Suspension for injection.

Clinical particulars

Target species

Cattle, pigs, dogs and cats.

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

Streptococci

Gram-negative

Actinobacillus lignierisi

Actinobacillus pleuropneumoniae

Bacteroides

Bordetella bronchiseptica

Campylobacter spp.

Escherichia coli

Fusobacterium necrophorum

Haemophilus spp.

Klebsiellae

Moraxella spp.

Pasteurellae

Proteus spp.

Salmonellae

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.

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.

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).

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.

Special warnings for each target species

None.

Special precautions for use

i) 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 areas 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.

The product may contain minute brown spots, which are considered to be an intrinsic characteristic of the formulation. Appearance of these spots will not adversely affect the safety or efficacy of the product.

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.

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.

Adverse reactions (frequency and seriousness)

Very rarely, the use of the product may 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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Use during pregnancy, lactation or lay

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

Interaction with other medicinal products and other forms of interaction

None known.

Amounts to be administered and administration route

By either intramuscular or subcutaneous injection in dogs and cats, and by intramuscular injection only in cattle and pigs, at a dosage rate of 8.75 mg/kg bodyweight (1 ml / 20 kg bodyweight) daily for 3-5 days.

Withdrawal periods

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:

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 ge teat of the infe
↓ 24 hours	↓
8.75 mg/kg bodyweight (7.0 mg amoxicillin, 1.75 mg clavulanic acid) i.e. 1 ml/20 kg bodyweight	One syringe ge teat of the infe
↓ 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, Synulox RTU Injection may be administered for an additional two days for a total of 5 daily injections	One syringe ge quarter

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 to be expected from an accidental overdose.

Withdrawal periods

Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cattle at 60 hours (5th milking, if cows are milked twice daily).

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. Pigs may be slaughtered for human consumption only after 31 days from the last treatment.

Combined Therapy: When using Synulox LC Intramammary and Synulox RTU 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 60

hours from the last treatment of Synulox RTU following the minimum posology regime as described in Section "Amounts to be administered and administration route".

Pharmacological particulars

Mode of action

Amoxicillin:

The mechanism by which β-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 β-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 β-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 β-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 β-lactamase activity, β-lactamases either form complexes with the antibiotic or cause a breakdown of the β-lactam ring. In either case the antibacterial activity is lost.

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

Pharmacokinetics

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.

Pharmaceutical particulars

List of excipients

Propylene Glycol Dicaprylocaprate

Incompatibilities

None known.

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.

Special precautions for storage

Do not store above 25°C.

This product does not contain an antimicrobial preservative. Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Nature and composition of immediate packaging

Type III glass vials of 40 and 100 ml, containing an off-white sterile, non-aqueous suspension. The vials are sealed with a rubber bung and an aluminium seal and packed in cartons containing 1 x 100 ml or 6 x 100 ml, and 1 x 40 ml or 12 x 40 ml. Each glass vial contains a sterile off-white to pale buff coloured, smooth fluid, readily dispersible suspension.

Not all pack sizes may be marketed.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

Marketing Authorisation Holder (if different from distributor)

UK (GB):

Zoetis UK Limited

UK (NI):

Zoetis Belgium S.A.

Marketing Authorisation Number

UK (GB):

Vm 42058/5174

UK (NI):

Vm 60021/3021

Significant changes

Date of the first authorisation or date of renewal

27 May 1987

Date of revision of the text

June 2024

Any other information

Legal category

Legal category:POM-V

GTIN

GTIN description:40 ml:

GTIN:05013457076905

GTIN description:100 ml:

GTIN:05013457076912