

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Ready-To-Use 140 mg/ml + 35 mg/ml suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Amoxicillin (as amoxicillin trihydrate)	140 mg
Clavulanic acid (as potassium clavulanate)	35 mg

Excipient:

Qualitative composition of excipients and other constituents

Propylene Glycol Dicaprylocaprate

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs, dogs, and cats.

3.2 Indications for use for each 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).

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal 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.

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.

People with known hypersensitivity to penicillins and cephalosporins should avoid contact with the veterinary medicinal product. 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, pigs, dogs, and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain, Injection site reaction. Allergic reaction ¹ (allergic skin reaction, anaphylaxis).
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¹ If allergic reaction occurs, discontinue use immediately. Treat symptomatically.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during the whole pregnancy, subject to observance of the withholding time for milk and the withdrawal time for meat intended for human consumption.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular or subcutaneous use in dogs and cats, and intramuscular use 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.

Shake 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
<p data-bbox="252 853 767 965">8.75 mg/kg bodyweight (7.0 mg amoxicillin, 1.75 mg clavulanic acid) i.e. 1 ml/20 kg bodyweight</p> <p data-bbox="437 987 592 1167">24 hours ↓</p> <p data-bbox="252 1256 767 1368">8.75 mg/kg bodyweight (7.0 mg amoxicillin, 1.75 mg clavulanic acid) i.e. 1 ml/20 kg bodyweight</p> <p data-bbox="437 1391 592 1570">24 hours ↓</p> <p data-bbox="252 1659 767 1771">8.75 mg/kg bodyweight (7.0 mg amoxicillin, 1.75 mg clavulanic acid) i.e. 1 ml/20 kg bodyweight</p> <p data-bbox="277 1805 742 1939">Where necessary, Synulox RTU Injection may be administered for an additional two days for a total of 5 daily injections</p>	<p data-bbox="831 853 1326 920">One syringe gently infused into the teat of the infected quarter</p> <p data-bbox="1018 954 1166 1032">12 hours ↓</p> <p data-bbox="831 1066 1326 1133">One syringe gently infused into the teat of the infected quarter</p> <p data-bbox="1018 1167 1166 1245">12 hours ↓</p> <p data-bbox="831 1290 1326 1357">One syringe gently infused into the teat of the infected quarter</p>

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The veterinary medicinal product 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle (meat and offal): 42 days.

Cattle (milk): 60 hours (5th milking, if cows are milked twice daily).

Pigs (meat and offal): 31 days.

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 3.9.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CR02

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Following either subcutaneous or intramuscular administration of the veterinary medicinal product 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

Do not store above 25 °C.
Keep the vial in the outer carton.
This product does not contain an antimicrobial preservative.

5.4 Nature and composition of immediate packaging

Colourless type III glass vial of 40 ml or 100 ml, closed with a chlorobutyl rubber stopper and sealed with an aluminium cap.

Pack sizes: Cardboard box with 1 x 100 ml, 6 x 100 ml, 1 x 40 ml or 12 x 40 ml vial(s).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A

7. MARKETING AUTHORISATION NUMBER

Vm 60021/3021

8. DATE OF FIRST AUTHORISATION

27 May 1987

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 16 December 2025

Gavin Hall