1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Ready to Use Injection 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
Fractionated coconut oil

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs, dogs and cats.

3.2 Indications for use for each target specie

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).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
The veterinary medicinal 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 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.

People with known hypersensitivity to Amoxicillin (as amoxicillin trihydrate) and Clavulanic acid (as potassium clavulanate) 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.

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] (e.g. allergic skin reaction, anaphylaxis)

[1] If occur, the product should be discontinued immediately. Appropriate symptomatic treatment should be initiated.

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 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.

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 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, Synulox RTU Injection may be administered for an additional two days for a total of five 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

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 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 (including combined therapy):
Meat and offal: 42 days.
Milk: 80 hours.

Pigs:
Meat and offal: 31 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CR02

4.2 Pharmacodynamics

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.

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.

Store in a dry place.

5.4 Nature and composition of immediate packaging

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

Pack sizes:
Containers containing 12 vials of 40 ml.
Containers containing 6 vials of 100 ml.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
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

VPA10387/075/001

8. DATE OF FIRST AUTHORISATION

02/05/2014

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

02/04/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).