

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**{Cardboard carton}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substances:**

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

**3. PACKAGE SIZE**

1 x 40 ml  
1 x 100 ml  
12 x 40 ml  
6 x 100 ml

**4. TARGET SPECIES**

Cattle, pigs, dogs, and cats.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Dogs and cats: subcutaneous or intramuscular use.  
Cattle and pigs: intramuscular use.

**7. WITHDRAWAL PERIODS**

Withdrawal periods:  
Cattle (meat and offal): 42 days.  
Cattle (milk): 60 hours (5<sup>th</sup> milking, if cows are milked twice daily).  
Pigs (meat and offal): 31 days.

**Combined therapy:** See package leaflet for details.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days, by: \_\_ / \_\_ / \_\_.

## **9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C.  
Keep the vial in the outer carton.

## **10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

## **11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

## **13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Zoetis Belgium S.A

## **14. MARKETING AUTHORISATION NUMBERS**

Vm 60021/3021

## **15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**  
**{100 ml Bottle label}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substances:**

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

**3. TARGET SPECIES**

Cattle, pigs, dogs, and cats.

**4. ROUTES OF ADMINISTRATION**

Dogs and cats: subcutaneous or intramuscular use.

Cattle and pigs: intramuscular use.

**5. WITHDRAWAL PERIODS**

Withdrawal periods:

Cattle (meat and offal): 42 days.

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

Pigs (meat and offal): 31 days.

**Combined therapy:** See package leaflet for details.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached, use within 28 days, by \_\_\_ / \_\_\_ / \_\_\_.

**7. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C.

Keep the vial in the outer carton.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Zoetis Belgium S.A

**9. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING**  
**UNITS**  
**{40 ml Bottle label}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Synulox Ready-to-Use

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Each ml contains:

**Active substances:**

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

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days, by \_\_ / \_\_ / \_\_.

## PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

### PACKAGE LEAFLET

#### 1. Name of the veterinary medicinal product

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

#### 2. Composition

Each ml contains:

##### Active substances:

Amoxicillin (as Amoxicillin trihydrate)	140 mg
Clavulanic acid (as Potassium clavulanate)	35 mg

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

#### 3. Target species

Cattle, pigs, dogs, and cats.

#### 4. Indications for use

The veterinary medicinal product has a notably broad spectrum of bactericidal activity against the bacteria commonly found in cattle, pigs, and small animals.

**Mode of Action:** Resistance to many antibiotics is caused by  $\beta$ -lactamase enzymes which destroy the antibiotic before it can act on the bacteria themselves. The clavulanate in the veterinary medicinal product counter-acts this defence mechanism by inactivating the  $\beta$ -lactamases, thus rendering the bacteria sensitive to amoxicillin's rapid bactericidal effect at concentrations readily attainable in the body.

**In vitro** the veterinary medicinal product 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*, *Peptostreptococcus* spp.

Gram-negative: *Escherichia coli* (including  $\beta$ -lactamase producing strains), Salmonellae (including  $\beta$ -lactamase producing strains), *Bordetella bronchiseptica*, *Campylobacter* spp., Klebsiellae, *Proteus* spp., Pasteurellae, *Fusobacterium necrophorum*, Bacteroides (including  $\beta$ -lactamase producing strains), *Haemophilus* spp., *Moraxella* spp., *Actinobacillus pleuropneumoniae* and *Actinobacillus lignieresii*.

##### Indications:

Cattle - respiratory infections, soft tissue infections (e.g. joint-ill, abscesses etc.) metritis and mastitis.

Pigs - respiratory bacterial infections in growing pigs, colibacillosis, periparturient infections in sows (e.g. mastitis-metritis-agalactia).

Dogs and cats - respiratory tract infections, urinary tract infections and skin and soft tissue infections (e.g. abscesses, pyoderma, anal sacculitis, gingivitis).

## **5. Contraindications**

In common with all other penicillins, the veterinary medicinal product should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in any other very small herbivores.

## **6. Special warnings**

None.

### Special precautions for safe use in the target species:

The suspension is not suitable for intravenous or intrathecal administration. Great care should be taken to avoid contaminating the remaining contents of the vial with water.

Clavulanic acid is moisture sensitive. It is very important, therefore, that a completely dry 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 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.

### 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.

Overdose:

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.

**7. 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 <sup>1</sup> (allergic skin reaction, anaphylaxis).
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<sup>1</sup> If allergic reaction occurs, discontinue use immediately. Initiate appropriate symptomatic treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

**8. Dosage for each species, routes and method of administration**

Dogs and cats: subcutaneous or intramuscular use.

Cattle and pigs: intramuscular use.

**Cattle, pigs, dogs and cats:** 8.75 mg/kg bodyweight, equivalent to 1 ml/20 kg bodyweight. Treatment should be administered once daily for 3 to 5 days.

**Combined therapy for the treatment of bovine mastitis:** in the situation where systemic 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 5 daily injections	

## 9. Advice on correct administration

Shake well before use.

Swab the septum before removing each dose. Use a completely dry sterile needle and syringe. Massage the injection site.

## 10. Withdrawal periods

Cattle (meat and offal): 42 days.

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

Pigs (meat and offal): 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 60 hours from the last treatment of Synulox RTU.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Do not store above 25 °C.  
Keep the vial in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

This product does not contain an antimicrobial preservative.

Shelf life after first opening the immediate packaging: 28 days.

## **12. Special precautions for disposal**

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBER AND PACK SIZES**

Vm 60021/3021

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.

## **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

Zoetis Belgium S.A.  
2nd Floor, Building 10  
Cherrywood Business Park  
Loughlinstown  
Dublin 19  
D18 T3Y1  
Ireland  
Tel: +353 (0) 1 256 9800

Manufacturer responsible for batch release:

Haupt Pharma Latina S.r.l.  
SS 156 Km 47,600  
06100 Borgo San Michele  
Latina  
Italy

## **17. Other information**

POM-V

Approved 16 December 2025

*Gavin Hall*