

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Stabox 50 mg/g premix for medicated feeding stuff for pigs

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each g contains:

#### **Active substance:**

Amoxicillin.....50mg  
(as Amoxicillin trihydrate)

#### **Excipients:**

<b>Qualitative composition of excipients and other constituents</b>
Polyvidone K 90
Rofelys (maize based)

Beige to brown powder with some white to yellow grains.

### **3. CLINICAL INFORMATION**

#### **3.1 Target species**

Pigs (weaned piglets)

#### **3.2 Indications for use for each target species**

For the treatment and metaphylaxis of diseases caused by *Streptococcus suis* in weaned piglets.

The presence of the disease in the group must be established before the product is used.

#### **3.3 Contraindications**

Do not use in cases of hypersensitivity to the active substance.

#### **3.4 Special warnings**

None.

### **3.5 Special precautions for use**

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

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of feed/water, animals should be treated parenterally. Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

#### 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 penicillin-containing products.

Handle this product with great care to avoid exposure, taking recommended precautions.

If you develop symptoms following exposure such as skin rash, seek medical advice immediately and show the package leaflet or the label to the physician.

Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and may require urgent medical attention.

When incorporating into feed, adequate measures must be taken not to create dust or to inhale any dust. Personal protective equipment consisting of a disposable half-mask respirator conforming to European Standard EN149 FFP1 (or non-disposable respirator to European Standard EN140 with a filter to EN143), coveralls, impervious gloves and safety glasses should be worn when handling the veterinary medicinal product.

Avoid skin contact.

Hands and exposed skin should be washed thoroughly after use.

Do not smoke or eat during use.

#### Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Pigs (weaned piglets):

Undetermined frequency (cannot be estimated from the available data):	Hypersensitivity reaction <sup>1</sup> (e.g. allergic reaction <sup>1</sup> )
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<sup>1</sup> May occasionally be serious.

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 its local representative or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Not applicable.

### 3.8 Interaction with other medicinal products and other forms of interaction

The bactericidal effect of amoxicillin is neutralised by simultaneous use of bacteriostatic acting pharmaceuticals.

### 3.9 Administration route and dosage

In-feed use.

For incorporation into dry feed at the registered mill.

A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products must be responsible for mixing when incorporation is less than 2kg per tonne for final feed.

15 mg of amoxicillin per kg of bodyweight daily for 14 consecutive days.

This dose may be achieved by the addition of:

- 1) 400 ppm or 8 kg of the veterinary medicinal product per tonne of feed in starter feed
- 2) 300 ppm or 6 kg of the veterinary medicinal product per tonne of feed in feed intended for piglets older than 6 weeks.

To ensure thorough dispersion, the product should first be mixed with a suitable quantity of feed before incorporation in the final mix.

The product can be incorporated into pelleted feed, preconditioned at a temperature not greater than 80°C, humidity of around 18 per cent and pressure of about 10 bars.

To ensure a correct dosage body weight should be determined as accurately as possible.

The intake of medicated feed depends on the clinical condition of the animal. In order to obtain the correct dosage, the concentration of the veterinary medicinal product has to be adjusted accordingly.

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

Penicillins have a wide margin of safety.

### **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**

Do not use for prophylaxis.

### **3.12 Withdrawal periods**

Meat and offal: 4 days

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code: QJ01CA04**

### **4.2 Pharmacodynamics**

The veterinary medicinal product contains 5% coated amoxicillin for oral administration to piglets as a medicated-feed supplement.

The formulation of this veterinary medicinal product is based on a new concept of coating the active ingredient. This method stabilises the amoxicillin and makes it less sensitive to temperature variations during storage, pelleting and storage of pelleted feed.

Amoxicillin is a bactericidal antibiotic of the beta-lactam family which acts by blocking the biosynthesis of the cell wall.

As a bactericidal antibiotic, amoxicillin inhibits the development of the peptidoglycan network structure of the bacterial cell wall. It is thought to act on transpeptidation which is the last step in the synthesis of the final bacterial-membrane structure.

Amoxicillin exerts very low M.I.C. values against *Streptococcus suis* type 2 (MIC 90 < 0.02 µg/ml) and is very active against other *Streptococcus* microorganisms, penicillinase staphylococci, *Corynebacteria* (*Actinomyces*, *Eubacteria*) *Clostridia*, *Bacillus anthracis* for the Gram-positive germs and *Campylobacter*, *Pasteurella*, *Escherichia coli*, *Salmonella*, *Brachyspira hyodysenteriae*, *Bordetella*, *Actinobacillus pleuropneumoniae* for the Gram-negative germs.

### **4.3 Pharmacokinetics**

When administered orally to 7-week-old piglets at the recommended dosage of 15 mg/kg bodyweight/day for 14 days, therapeutic plasma levels were maintained throughout the treatment.

Amoxicillin is mainly excreted in the urine under its natural form and as penicilloic acid.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

None known.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years  
Shelf life after incorporation into meal or pelleted feed: 6 months.

### **5.3 Special precautions for storage**

Store below 30°C  
Store in the original container.  
Store in a dry place.

### **5.4 Nature and composition of immediate packaging**

Pack sizes: 1 kg can, 6 kg, 5 kg, 8 kg, 10 kg, 20 kg, 25 kg and 50 kg bags

1 kg cans are made of white high density polyethylene stopped by a yellow high density polyethylene screw-fit lid.

6 kg, 8 kg, 10 kg, 20 kg and 50 kg bags are made of 4 layers: low density polyethylene film /paper/ paper/ external film made of paper, polyethylene and aluminium complex.

5 and 25 kg bags are made of 4 layers: low density polyethylene film / paper / film made of paper, polyethylene and aluminium complex/ external paper film.

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 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**

VIRBAC

## **7. MARKETING AUTHORISATION NUMBER**

Vm 05653/4044

**8. DATE OF FIRST AUTHORISATION**

02 November 1995

**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](http://www.gov.uk).

*Gavin Hall*  
Approved: 17 December 2025