

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stabox 5% w/w Premix for Medicated Feeding Stuff For Piglets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s)	% w/w
Amoxicillin..... (as Amoxicillin Trihydrate)	5%

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Premix for Medicated feeding Stuff.
Beige to brown powder with some white to yellow grains.

4. CLINICAL PARTICULARS

4.1 Target species

Weaned piglets

4.2 Indications for use, specifying the target species

For the control of diseases caused by *Streptococcus suis* in weaned piglets.

4.3 Contraindications

None known.

4.4 Special warnings for each target species

No special warnings

4.5 Special precautions for use

i. Special precautions for use in animals

Whenever possible, Stabox should only be used based on susceptibility testing.

Official, national and regional antimicrobial policies should be taken into account when the product is used.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Adequate measures must be taken not to create dust when incorporation of the product into feed is occurring. Whilst handling the product wear coveralls, protective goggles and chemically resistant impermeable

gloves all times.

Avoid inhalation of dust.

Wear either a disposable half-mask respirator conforming to European Standard EN149 or non-disposable respirator to European Standard EN140 with a filter to EN143.

Do not smoke or eat during use.

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.

- (1) Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
- (2) Handle this product with great care to avoid exposure, taking all recommended precautions.
- (3) If you develop symptoms following exposure such as 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.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Not applicable

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amount(s) to be administered and administration route

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 or bodyweight daily for 14 consecutive days.

This dose may be achieved by the addition of :

- 1) 400 ppm or 8 kg of Stabox per ton of feed in starter feed
- 2) 300 ppm or 6 kg of Stabox per ton 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 to avoid underdosing.

The intake of medicated feed depends on the clinical condition of the animal. In

order to obtain the correct dosage, the concentration of Stabox has to be adjusted accordingly.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Penicillins have a wide margin of safety.

4.11 Withdrawal period(s)

Meat : 4 days

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: J01CA04

Pharmacotherapeutic group: Antiinfectives for systemic use

5.1 Pharmacodynamic properties

Stabox contains 5% coated amoxicillin for oral administration to piglets as a medicated-feed supplement.

The formulation of Stabox 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, *Corynebacteria* (*Actinomyces*, *Eubacteria*) *Clostridia*, *Bacillus anthracis* for the gram-positive bacteria and *Pasteurella*, *Escherichia coli*, *Salmonella*, *Bordetella* for the gram-negative bacteria.

5.2 Pharmacokinetic properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone K90
Rofelys

6.2 Major incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

Store in tightly-closed original container.
Store in a dry place.
Do not store above 30°C
Avoid extremes of temperature.
Once incorporate into pelleted feed, use the product within 6 months.

6.5 Nature and composition of immediate packaging

1 kg white high density polyethylene can with yellow high density polyethylene lid. (screw-fit).

6 kg, 8 kg, 10 kg, 20 kg and 50 kg low density polyethylene, paper and aluminium complex/paper/paper/50 µm low density polyethylene film bags.

- Small format 1 paper layer / complex paper/LDPE/Alu / 1 paper layer /polyethylene low density bag (5 kg).
- Large format 1 paper layer / complex paper/LDPE/Alu / 1 paper layer / polyethylene low density bag (25 kg).

Not all pack sizes may be marketed

6.6 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 medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4044

9. DATE OF FIRST AUTHORISATION

02 November 1995

10. DATE OF REVISION OF THE TEXT

January 2022

Approved: 12/01/22

A handwritten signature in black ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending to the right from the end of the name.