Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Stabox 5g Premix for medicated feeding stuff

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	
Amoxicillin (as trihydrate)	5 g
Excipients	
Polyvidone K 90	235 mg
Rofleys	up to 100 g

3 PHARMACEUTICAL FORM

A 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 treatment and prevention of diseases caused by *Streptococcus suis* in weaned piglets

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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.

Special precautions to be taken by the person administering the medicinal product to animals

When incorporating into feed care should be taken not to inhale any dust. It is recommended to use a dust mask (EN 149 FFP1). The operator should also wear impervious gloves and safety glasses. Adequate measures must be taken not to create dust when incorporation into the feed is occurring.
When handling the product, skin contact should be avoided. Hands and exposed skin should be washed thoroughly at the end of the operation. 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, you should seek medical advice. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and may require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Penicillins and cephalosporins may cause hypersensitivity following administration. Allergic reaction to these substances may occasionally be serious.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

For oral administration.

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

This dose may be achieved by the addition of:
1) 400 ppm or 8 kg STABOX per tonne feed in starter feed.

2) 300 ppm or 6 kg STABOX per tonne 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.

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

Not applicable

4.11 Withdrawal period(s)

Meat: 4 days. Animals must not be slaughtered for human consumption during treatment. Animals intended for human consumption may be slaughtered after 4 days from last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterial
ATCvet Code: QJ01CA04.

5.1 Pharmacodynamic properties

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

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.

5.2 Pharmacokinetic particulars

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, Clostridia, Bacillus anthraci for the gram positive germs and Campylobacter, Pasteurella, Escherichia coli, Salmonella, Serpolina hyodysenteria, Bordetella, Actinobacillus pleuropneumoniae for the gram negative germs.

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

Polyvidone K90
*Rofelys

* Maize based

6.2 Major incompatibilities

Not applicable.

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 below 30°C.
Store in the original package.

6.5 Nature and composition of immediate packaging

1 kg cans made of white high density polyethylene stopped by a yellow high density polyethylene lid.
- 6, 8, 20 and 50 kg bags made of 4 successive layers
- a 50 µm polyethylene film
- two kraft paper films
- an external film made of a paper, polyethylene and aluminium complex.
- 25 kg bags made of 4 successive layers:
- a 50-µm polyethylene film;
- one kraft-paper film;
- a paper, polyethylene and aluminium complex.
- an external film made of one kraft-paper film.

Not all pack sizes may be marketed.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Virbac
1ère avenue
2065 M LID
06516 Carros
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/052/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10th July 2007

10 DATE OF REVISION OF THE TEXT

July 2018