SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STABOX 50% ww/ww Powder for Oral Solution for Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Amoxicillin (as trihydrate form) .....500.00 mg

Excipient(s):
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral solution.
White to almost white and slightly granular powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pig (pigs after weaning).

4.2 Indications for use, specifying the target species

Treatment of swine pleuropneumonia due to *Actinobacillus pleuropneumoniae* (susceptible to amoxicillin).

4.3 Contraindications

- Do not use in animals with known hypersensitivity to penicillins or other substances of the ß-lactam group.
- Do not use in animals with serious kidney malfunction including anuria and oliguria.
- Presence of β - lactamase producing bacteria.
- Do not use in lagomorphs and rodents such as rabbits, guinea pigs, hamsters or gerbils.
- Do not use in ruminants or horses.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. 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.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal.
If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin.

Narrow spectrum antibacterial therapy should be used for first line treatment where susceptibility testing suggest the likely efficacy of this approach.

ii. 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 such preparations.
- 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.
- Use inhalation protection and gloves during preparation.
- Use gloves during the administration of the liquid feed to the pigs.
- Wash the exposed skin.
- Avoid introduction of contamination during the administration of the product.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

Studies performed in Laboratory animals (rat, rabbit), did not show a teratogenic, embryotoxic or maternotoxic effect of amoxicillin. Safety of the product in the pregnant and lactating sows was not demonstrated. Use only accordingly to the benefit/risk assessment by the responsible veterinarian

4.8 Interaction with other medicinal products and other forms of interaction

The bactericidal effect of amoxicillin is neutralized by simultaneous use of pharmaceuticals with bacteriostatic mode of action.
Not to be used simultaneously with neomycin since it blocks the absorption of oral penicillins.

4.9 Amounts to be administered and administration route

- 20 mg of amoxicillin (as trihydrate) per kg body weight daily (i.e. 400 mg of the product per 10 kg body weight per day), administered for 5 consecutive days orally in liquid feed.
- Shake the product container well before use.
- After dilution of the product in a small quantity of water, the dilution must be mixed in the liquid meal until homogenous.
- The required amount of product should be weighed as accurately as possible using a suitably calibrated weighing equipment.
- Use in commercial feed only.

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 animals. In order to obtain the correct dosage the concentration of Suramox has to be adjusted accordingly.

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

No side effects were observed after administration at 5 times the recommended dosage.

4.11 Withdrawal period(s)

Meat and offal: 14 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Penicillins with extended spectrum.

ATCvet code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin is a semi-synthetic penicillin derived from the 6 APA core (6 amino-penicillic acid). It is a broad spectrum antibiotic, bactericidal against Gram+ and Gram- bacteria, in particular *Actinobacillus pleuropneumoniae*, isolated in pigs.

Amoxicillin acts by inhibition of bacterial cell wall synthesis or activation of enzymes disrupting cell walls (bactericidal action).

5.2 Pharmacokinetic particulars

In pigs, after the administration of the product at a dose of 20 mg/kg in liquid feed, amoxicillin maximal plasma concentration of 2.0 µg/ml is reached 1.8 hours after the administration. The repeated administration of the drug does not lead to accumulation. The average absolute bioavailability of amoxicillin in liquid feed is estimated to be 12%.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium glycine carbonate,
Colloidal anhydrous silica,
Vanillin,
Sodium hexametaphospate.

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the container: 10 days
Shelf-life after dissolution in liquid feed: 2 hours.

6.4. Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

- 1 box with 50 g high density polyethylene jar hermetically closed by thermosealed aluminium polyethylene seal and over screw cap.
- 1 box with 100 g high density polyethylene jar hermetically closed by thermosealed aluminium polyethylene seal and over screw cap.
- 200 g high density polyethylene jar hermetically closed by thermosealed aluminium polyethylene seal and over screw cap.
- 500 and 1000 g high density polyethylene jars hermetically closed by thermosealed aluminium polyethylene seal and over screw cap.
- 1500 and 3000 g high density polyethylene barrels closed hermetically by screw caps equipped with an internal rubber seal and an external security compact seal.
- 500, 1000 and 2000 g multi-layer (low density polyethylene / aluminium / polyethyleneterephtalate) stand up pouches equipped with a zip.
- 3000 g multi-layer (low density polyethylene / aluminium / polyethyleneterephtalate) stand up pouches equipped with a zip and a handle.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

Vm 05653/4115

9. DATE OF RENEWAL OF THE AUTHORISATION

Date: 10 January 2010

10. DATE OF REVISION OF THE TEXT

Date: January 2013

Approved :
18/01/13