SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stabox 1000 mg/g powder for use in drinking water for chickens, ducks, turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1.0 g powder contains:

Active substance:
Amoxicillin trihydrate 1000 mg (equivalent to 871.24 mg amoxicillin)

3. PHARMACEUTICAL FORM

Powder for use in drinking water
White or almost white, crystalline powder

4. CLINICAL PARTICULARS

4.1 Target species

Chicken, duck, turkey

4.2 Indications for use, specifying the target species

Treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin.

4.3 Contraindications

Do not use in rabbits, hamsters, gerbils and guinea pigs.
Do not use in ruminants and horses.
Do not use in known cases of hypersensitivity to penicillins or to other β-lactam antibiotics.
Do not treat infections caused by bacteria producing the enzyme beta lactamase.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

Official, national and regional antimicrobial policies should be taken into account when the product is used.
Resistance against amoxicillin may vary. 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 the amoxicillin and may decrease the effectiveness of the treatment.

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

Persons handling this product should avoid inhalation of any dust and contact with skin.
Wear either disposable half-mask respirator conforming to European Standard EN 149 or a non-disposal respirator to European Standard EN 140 with filter EN 143 when mixing or applying this product.
Impermeable gloves should be worn when mixing or applying this product.
Hands and exposed skin should be washed thoroughly after 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.
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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases penicillins and cephalosporins may cause hypersensitivity reactions following administration. Allergic reactions to these substances may occasionally be serious.

The frequency of adverse reactions is defined using the following convention:
-very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
-common (more than 1 but less than 10 animals in 100 animals)
-uncommon (more than 1 but less than 10 animals in 1,000 animals)
-rare (more than 1 but less than 10 animals in 10,000 animals)
-very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin.

Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Amoxicillin exerts its bactericidal action by inhibition of bacterial cell wall synthesis during multiplication. It is therefore in principle not compatible with bacteriostatic antibiotics (e.g. tetracyclines, macrolides and sulphonamides) which inhibit multiplication. Synergism occurs with ß-lactam antibiotics and aminoglycosides.
Not to be used simultaneously with neomycin since it blocks the absorption of oral penicillins.

4.9 Amounts to be administered and administration route

For use in drinking water.
The following formula may be used to calculate the amount of product required per day (in grams):

$$\frac{\text{dose in mg product per kg bodyweight per day} \times \text{total bodyweight (kg) of all treated animals}}{\text{total daily water consumption of all treated animals (litres)}} = \text{mg of product / litre drinking water}$$

Chickens:
The recommended dosage is 15 mg amoxicillin trihydrate per kg bodyweight.
The total period of treatment should be for 3 consecutive days or in severe cases for 5 consecutive days.

Ducks:
Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight for 3 consecutive days.

Turkeys:
Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight for 3 consecutive days or in severe cases for 5 consecutive days.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. The uptake of medicated water depends on the clinical condition of the birds. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted taking into account water intake.

Prepare the solution with fresh tap water immediately before use.
Any unused medicated water should be discarded after 24 hours.

In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated. The use of suitably calibrated weighing equipment for the administration of the calculated amount of the product is recommended.

Solubility in water varies depending on temperature and water quality as well as on time and intensity of stirring. Under worst case conditions (10°C and soft water) maximum solubility is approximately 1.0 g/l but increases by raising temperature. At 25°C and in hard water maximum solubility is increased to at least 2 g/l.

For stock solutions and for use of a proportioner: Take care not to exceed maximum solubility which can be achieved under the given conditions. Adjust flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals treated. Moderate increase of temperature and constant stirring can help to raise solubility.

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

No side effects were observed after administration at 5 times the recommended dosage. Treatment should be symptomatic and no specific antidote is available.

4.11 Withdrawal period(s)

Chicken (meat & offal)	1 day
Duck (meat & offal)	9 days
Turkey (meat & offal)	5 days

The product is not authorised for use in laying birds producing eggs for human consumption and within 3 weeks of onset of laying.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-Lactam antibiotic Penicillins
ATCvet code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin is a time-dependent bactericidal antibiotic belonging to the semisynthetic penicillin group which acts by inhibiting the synthesis of bacterial cell walls during bacterial replication. It has a broad spectrum of activity against Gram positive and Gram negative bacteria, and owes its activity to the inhibition of the development of the peptidoglycan network structure in the bacterial cell wall.

There are three main mechanisms of resistance to beta-lactams: beta-lactamase production, production of penicillin binding proteins, and decreased penetration of the outer membrane. One of the most important is the inactivation of penicillin by beta-lactamase enzymes produced by certain bacteria. These enzymes are capable of cleaving the beta-lactam ring of penicillins, making

them inactive. The beta-lactamase could be encoded in chromosomal or plasmidic genes.
Cross-resistance is observed between amoxicillin and other penicillins, particularly with aminopenicillins.

5.2 Pharmacokinetic particulars

Amoxicillin is well absorbed following oral administration and it is stable in the presence of gastric acids. Excretion of amoxicillin is mainly in the unchanged form via the kidneys to give high concentration in renal tissue and urine. Amoxicillin is well distributed in body fluids.

For chickens, amoxicillin is quickly absorbed with Tmax (=1hr) and amoxicillin concentrations < 0.25 µg/ml after 6 hours after a dose of 10 mg/kg.
For turkeys, at a dose rate of 10 mg/kg, the Cmax was lower than seen in chickens.
For ducks, an oral dose of 20 mg/kg decreased to below a level of 0.25 µg/ml by 5 hours after administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Major Incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 3 months
Shelf-life after dilution or reconstitution according to directions: 24 hours

6.4 Special precautions for storage

After opening, do not store above 25ºC.
Keep the bag tightly closed after first opening in order to protect from moisture and light.
Any medicated water which has not been consumed within 24 hours, should be discarded.

6.5 Nature and composition of immediate packaging

100 g, 500 g, 1000 g and 5000 g in aluminum bags (PET – ALU – LDPE)
The 5000 g bag will be provided with a zip lock.

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 product 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 05653/4207

9. DATE OF FIRST AUTHORISATION

16 December 2013

10. DATE OF REVISION OF THE TEXT

August 2018

Approved: 14 August 2018