LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{Alu Bag, immediate package}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Amoxicillin trihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

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

4. PACKAGE SIZE

100 g
500 g
1000 g
5000 g

5. TARGET SPECIES

Chicken, duck, turkey

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

Withdrawal period:

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.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings
Penicillins and cephalosporins may occasionally cause severe allergic reactions.
See package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}>
Once broached,/opened, use by…
Shelf-life after first opening the immediate packaging: 3 months
Shelf-life after dilution or reconstitution according to directions: 24 hours

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder
Virbac
1ère avenue - 2065m - LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER

Vm 05653/4207

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
Virbac
1ère avenue - 2065m - LID
06516 Carros
France

Manufacturing authorisation holder responsible for batch release
aniMedica Herstellungs GmbH
Pappelstrasse 7
72160 Horb
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Amoxicillin trihydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1.0 g powder contains:

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

4. INDICATION(S)

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

5. 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, other β-lactam antibiotics or to any of the excipients.
Do not treat infections caused by bacteria producing the enzyme beta lactamase.

6. ADVERSE REACTIONS

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system *{national system details}*.

7. TARGET SPECIES

Chicken, ducks, turkeys.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The product is administered in the 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 and pH. 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.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Chickens (meat & offal): 1 day
Ducks (meat & offal) : 9 days
Turkeys (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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Shelf-life after dilution or reconstitution according to directions: 24 hours
Shelf-life after first opening the immediate packaging 3 months
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.
Do not use after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special warnings for each target species
None.

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.

User warnings
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-disaposal respirator to European Standard EN 140 with a filter to EN 143 when mixing or applying this product.
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.

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.

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.

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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{MM/YYYY}

15. OTHER INFORMATION

Package sizes: 100 g, 500 g, 1000 g, 5000 g. Not all pack sizes may be marketed.

Approved: 14 August 2018