ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 50 g or 100 g
Jar of 200 g or 500 g or 1 kg
Barrel of 1,5 kg or 3 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stabox 50 % ww Powder for Oral Solution for Pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains:
Amoxicillin (as trihydrate form) .....500.00 mg

3. PHARMACEUTICAL FORM

Powder for oral solution.

4. PACKAGE SIZE

50 g
100 g
200 g
500 g
1 kg
1,5 kg
3 kg

5. TARGET SPECIES

Pig.

6. INDICATION(S)

Read the package leaflet before use.
If you notice serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
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 Suramox has to be adjusted accordingly.

10. EXPIRY DATE

EXP: {month/year}
Once opened, use within 10 days.
After dissolution in liquid feed, use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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

Read the package leaflet before use.

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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4115

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Jar of 50 g or 100 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stabox 50 % ww Powder for Oral Solution for Pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each gram contains:
Amoxicillin (as trihydrate form) .....500.00 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 g
100 g

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD

Meat and offal: 14 days.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
Read the package leaflet before use.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Box of 50 g or 100 g
Jar of 200 g or 500 g or 1 kg
Barrel of 1,5 kg or 3 kg

STABOX 50 % ww Powder for Oral Solution for Pigs

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

Marketing authorisation manufacturer for the batch release:
FC France SAS
8-10 rue des Aulnaies
95420 Magny-En-Vexin
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

STABOX 50 % ww Powder for Oral Solution for Pigs

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

Each gram contains:

Active substance:

Amoxicillin (as trihydrate form) .....500.00 mg

4. INDICATION(S)

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

5. 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.

6. ADVERSE REACTIONS

Penicillins and cephalosporins may cause hypersensitivity following administration. Allergic reactions to these substances may occasionally be serious.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pig (pigs after weaning).

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

- 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.

10. WITHDRAWAL PERIOD

Meat and offal: 14 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date which is stated on the label and carton after EXP.
Shelf-life after first opening the container: 10 days
Shelf-life after dissolution in liquid feed: 2 hours.

12. SPECIAL WARNING(S)

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.

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.

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

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.

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

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

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 products should be disposed of in accordance with local national requirements.

14. DATE ON WICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2021

15. OTHER INFORMATION

- 1 box with a 50 g jar.
- 1 box with a 100 g.
- 200 g jar.
- 500 and 1000 g jars.
- 1500 and 3000 g barrels.
- 500, 1000, 2000 and 3000 g pouches.

Not all pack sizes may be marketed.

When the container is opened for the first time, using the in use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label."

PARTICULARS TO APPEAR ON THE OUTER PACKAGE / PACKAGE LEAFLET

Pouch of 500 g or 1000 g or 2000 g or 3000 g

STABOX 50 % ww Powder for Oral Solution for Pigs

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2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Each gram contains:

Active substance:

Amoxicillin (as trihydrate form) .....500.00 mg

4. INDICATION(S)

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  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.

10. WITHDRAWAL PERIOD

Meat and offal: 14 days.

11. SPECIAL STORAGE PRECAUTIONS

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Batch: {number}
EXP: {month/year}

Approved 03 February 2022