MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET – Outer label

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

Virbac S.A.
1 ère avenue – 2065 m – L.I.D.
06516 Carros
France

Manufacturer : FC France SAS - 8-10 rue des Aulnaies - 95420
Magny-en-Vexin – France

Distributed by Virbac Ltd - Windmill Avenue - Woolpit
Business Park - Woolpit - Bury St Edmunds -
Suffolk IP30 9UP - United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stabox 5% w/w Premix for Medicated Feeding Stuff For Piglets

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

Active substance(s)
Amoxicillin…… 5% w/w
(as Amoxicillin Trihydrate)

4. PHARMACEUTICAL FORM

Premix for Medicated feeding Stuff.

5. PACKAGE SIZE

25 kg

6. INDICATION(S)

For the control of diseases caused by Streptococcus suis in weaned piglets.

Whenever possible, Stabox should only be used based on susceptibility testing. Official, national and regional antimicrobial policies should be taken into account when the product is used.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Weaned piglets.

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

RECOMMENDED DOSE AND DOSAGE SCHEDULE

The dosage is 15 mg of amoxicillin per kg of bodyweight daily for 14 consecutive days.
This dose may be achieved by the addition of :
1) 400 ppm or 8 kg of STABOX per ton of feed in starter feed
2) 300 ppm or 6 kg of STABOX per ton of 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.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The intake of the medicated feed depends of the clinical condition of the animals. In order to aim the correct dosage the concentration of Stabox has to be adjusted accordingly.

The product can be incorporated into pelleted feed preconditioned at a temperature not greater than 80 °C, humidity of around 18 % and pressure of about 10 bars.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment. Piglets may be slaughtered for human consumption only after 4 days from the end of last treatment.

13. SPECIAL STORAGE PRECAUTIONS

PHARMACEUTICAL WARNINGS
Do not store above 30 °C. Store in a dry place. Store in tightly-closed original container. Avoid extremes of temperature. Once incorporated into pelleted feed, use the product within 6 months.

14. SPECIAL WARNING(S)

OPERATOR WARNINGS
Adequate measures must be taken not to create dust when incorporation of the product into feed is occurring. Whilst handling the product wear coveralls, protective goggles and chemically resistant impermeable gloves all times. Avoid inhalation of

dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or non-disposable respirator to European Standard EN140 with a filiter to EN143. Do not smoke or eat during 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.
(1) Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
(2) Handle this product with great care to avoid exposure, taking all recommended precautions.
(3) If you develop symptoms following exposure such as 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. When handling the product, skin contact should be avoided.
WASH HANDS AFTER USE.
For incorporation into dry feed at the registered mill. A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

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

Dispose of any unused product and empty container in accordance with guidance from your local waste-regulation authority.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

November 2021

18. 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
POM-V U.K.
Authorised veterinary medicinal product

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF REACH OF CHILDREN

20. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4044

21. MANUFACTURER'S BATCH NUMBER

Batch: number

22. OTHER INFORMATION

This pack contains 1250 g of amoxicillin (as trihydrate)

Approved: 24/11/21