

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet
IE: 1 kg can and 6-8-20-25-50 kg bags
UK: 1 kg can and 5-6-8-10-20-25-50 kg bags

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stabox 50 mg/g premix for medicated feeding stuff for pigs

2. COMPOSITION

Each g contains:

Active substance:

Amoxicillin..... 50 mg
(as Amoxicillin trihydrate)

Beige to brown powder with some white to yellow grains.

3. PACKAGE SIZE

1 kg
5 kg {For UK only}
6 kg
8 kg
10 kg {For UK only}
20 kg
25 kg
50 kg

4. TARGET SPECIES

Pigs (weaned piglets)

5. INDICATIONS FOR USE

Indications for use

For the treatment and metaphylaxis of diseases caused by *Streptococcus suis* in weaned piglets.

The presence of the disease in the group must be established before the product is used.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of hypersensitivity to the active substance.

7. SPECIAL WARNINGS

Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

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. Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

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 penicillin-containing products.

Handle this product with great care to avoid exposure, taking recommended precautions.

If you develop symptoms following exposure such as skin rash, seek medical advice immediately and show the package leaflet or the label to the physician.

Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and may require urgent medical attention.

When incorporating into feed, adequate measures must be taken not to create dust or to inhale any dust. Personal protective equipment consisting of a disposable half-mask respirator conforming to European Standard EN149 FFP1 (or non-disposable respirator to European Standard EN140 with a filter to EN143), coveralls, impervious gloves and safety glasses should be worn when handling the veterinary medicinal product.

Avoid skin contact.

Hands and exposed skin should be washed thoroughly after use.

Do not smoke or eat during use.

Interaction with other medicinal products and other forms of interaction:

The bactericidal effect of amoxicillin is neutralised by simultaneous use of bacteriostatic-acting pharmaceuticals.

Overdose:

Penicillins have a wide margin of safety.

Major incompatibilities:

None known.

Special restrictions for use and special conditions for use:

Do not use for prophylaxis

8. ADVERSE EVENTS

Adverse events

Pigs (weaned piglets):

Undetermined frequency (cannot be estimated from the available data):

Hypersensitivity reaction ¹ (e.g. allergic reaction ¹)

¹ May occasionally be serious.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details on this label, or via your national reporting system:

IE:

HPRA Pharmacovigilance

Website: www.hpra.ie

UK:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In-feed use.

For incorporation into dry feed at the registered mill.

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 the veterinary medicinal product per tonne of feed in starter feed
- 2) 300 ppm or 6 kg of the veterinary medicinal product per tonne of feed in feed intended for piglets older than 6 weeks.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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.

To ensure thorough dispersion, the product should first be mixed with a suitable quantity of feed before incorporation in the final mix.

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.

To ensure a correct dosage body weight should be determined as accurately as possible.

The intake of the medicated feed depends on the clinical condition of the animals. In order to aim for the correct dosage the concentration of the veterinary medicinal product has to be adjusted accordingly.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 4 days

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Store below 30 °C.

Store in the original container.

Store in a dry place.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

UK: Vm 05653/4044

Pack sizes: 1 kg can, 6 kg, 5 kg, 8 kg, 10 kg, 20 kg, 25 kg and 50 kg bags

Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder:
VIRBAC
1ère avenue 2065 m LID
06516 Carros
France

Manufacturer responsible for batch release:

FC France SAS
8 rue des Aulnaies
95420 Magny-en-Vexin
France

Local representative and contact details to report suspected adverse events:

VIRBAC IRELAND
McInerney & Saunders
38, Main Street
Swords, Co Dublin
K67E0A2
Republic Of Ireland
Tel: +44 (0)-1359 243243

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. OTHER INFORMATION

Other information

IE : POM (Prescription Only)

UK: POM-V

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after incorporation into meal or pelleted feed: 6 months.

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 17 December 2025