

**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 500 mg/g powder for oral solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

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

**3. PACKAGE SIZE**

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

**4. TARGET SPECIES**

Pig (weaned piglet).

**5. INDICATION(S)**

**6. ROUTES OF ADMINISTRATION**

Oral use.

**7. WITHDRAWAL PERIODS**

Withdrawal period:  
Meat and offal: 14 days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use within 10 days.  
Once dissolved in liquid feed, use within 2 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

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

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

VIRBAC

**14. MARKETING AUTHORISATION NUMBERS**

Vm 05653/3039

**15. BATCH NUMBER**

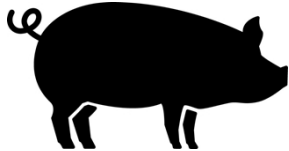
Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Jar of 50 g or 100 g

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

STABOX



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

500.00 mg/g

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

## **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**

**1. Name of the veterinary medicinal product**

STABOX 500 mg/g powder for oral solution for pigs

**2. Composition**

Each gram contains:

**Active substance:**

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

White to almost white and slightly granular powder.

**3. Target species**

Pig (weaned piglet).

**4. Indications for use**

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

**5. Contraindications**

Do not use in cases of hypersensitivity to penicillins or other substances of the  $\beta$ -lactam group or to any of the excipient(s).

Do not use in animals with serious kidney malfunction including anuria and oliguria.

Do not use in case of presence of  $\beta$ -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. Special warnings**

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.

Use of the veterinary medicinal 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 veterinary medicinal product deviating from the instructions given in the Package Leaflet 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 veterinary medicinal product if you know you are sensitised, or if you have been advised not to work with such preparations.***

***Handle this veterinary medicinal 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 veterinary medicinal product.***

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in sows.

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, embryotoxic or maternotoxic effects of amoxicillin.

Use only according 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.

Do not use simultaneously with neomycin as it blocks the absorption of oral penicillins.

Overdose:

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

Major incompatibilities:

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

## **7. Adverse events**

Pig (weaned piglet):

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

Hypersensitivity reaction <sup>1</sup> (e.g. allergic reaction <sup>1</sup> )
---

<sup>1</sup> May be caused by penicillins and cephalosporins. 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 in this package leaflet, 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 using the contact details at the end of this leaflet, or via your national reporting system:

E-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

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

## **8. Dosage for each species, routes and method of administration**

Oral use.

20 mg of amoxicillin (as trihydrate) per kg body weight daily (i.e. 400 mg of the veterinary medicinal product per 10 kg body weight and per day), administered for 5 consecutive days orally in liquid feed.

The required amount of veterinary medicinal product should be weighed as accurately as possible using a suitably calibrated weighing equipment.

## **9. Advice on correct administration**

Shake the veterinary medicinal product container well before use.

After dilution of the veterinary medicinal product in a small quantity of water, the dilution must be mixed in the liquid meal until homogenous.

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 amoxicillin has to be adjusted accordingly.

## **10. Withdrawal periods**

Meat and offal: 14 days.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp.

Shelf life after first opening the immediate packaging: 10 days.  
Shelf life after dissolution in liquid feed: 2 hours.

## **12. 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.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

Vm 05653/3039

Box with a 50 g jar.  
Box with a 100 g jar.  
200 g jar.  
500 and 1000 g jars.  
1500 and 3000 g barrels.

Not all pack sizes may be marketed.

## **15. 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](http://www.gov.uk).

## **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

VIRBAC  
1<sup>ère</sup> avenue 2065m LID  
06516 Carros  
France

Manufacturer responsible for batch release:

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

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET**

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

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

STABOX 500 mg/g powder for oral solution for pigs

**2. COMPOSITION**

Each gram contains:

**Active substance:**

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

White to almost white and slightly granular powder.

**3. PACKAGE SIZE**

500 g  
1000 g  
2000 g  
3000 g

**4. TARGET SPECIES**

Pig (weaned piglet).

**5. INDICATIONS FOR USE**

**Indications for use**

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

**6. CONTRAINDICATIONS**

**Contraindications**

Do not use in cases of hypersensitivity to penicillins or other substances of the  $\beta$ -lactam group, or to any of the excipient(s).

Do not use in animals with serious kidney malfunction including anuria and oliguria.

Do not use in case of presence of  $\beta$ -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.

## 7. SPECIAL WARNINGS

### Special warnings

#### 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.

Use of the veterinary medicinal 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 veterinary medicinal product deviating from the instructions given in the Label 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 **veterinary medicinal** product if you know you are sensitised, or if you have been advised not to work with such preparations.***

***Handle this veterinary medicinal 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 veterinary medicinal product.***

#### Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in sows.

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, embryotoxic or maternotoxic effects of amoxicillin.

Use only according 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.

Do not use simultaneously with neomycin as it blocks the absorption of oral penicillins.

Overdose:

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

Major incompatibilities:

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

**8. ADVERSE EVENTS**

**Adverse events**

Pig (weaned piglet):

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

Hypersensitivity reaction<sup>1</sup> (e.g. allergic reaction<sup>1</sup>)

<sup>1</sup> May be caused by penicillins and cephalosporins. 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 using the contact details on this label, or via your national reporting system:

E-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

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

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

**Dosage for each species, routes and method of administration**

Oral use.

20 mg of amoxicillin (as trihydrate) per kg body weight daily (i.e. 400 mg of the veterinary medicinal product per 10 kg body weight and per day), administered for 5 consecutive days orally in liquid feed.

The required amount of veterinary medicinal product should be weighed as accurately as possible using a suitably calibrated weighing equipment.

## **10. ADVICE ON CORRECT ADMINISTRATION**

### **Advice on correct administration**

Shake the veterinary medicinal product container well before use.  
After dilution of the veterinary medicinal product in a small quantity of water, the dilution must be mixed in the liquid meal until homogenous.  
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 amoxicillin has to be adjusted accordingly.

## **11. WITHDRAWAL PERIODS**

### **Withdrawal periods**

Meat and offal: 14 days.

## **12. SPECIAL STORAGE PRECAUTIONS**

### **Special storage precautions**

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp.

## **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

Vm 05653/3039

### Pack sizes

500, 1000, 2000 and 3000 g pouches.

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](http://www.gov.uk).

## 17. CONTACT DETAILS

### Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

VIRBAC  
1<sup>ère</sup> avenue 2065m LID  
06516 Carros  
France

Manufacturer responsible for batch release:

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

## 18. OTHER INFORMATION

**19. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**20. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use within 10 days.

Once dissolved in liquid feed, use within 2 hours.

**21. BATCH NUMBER**

Lot {number}

*Gavin Hall*  
Approved: 07 February 2025