ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SURAMOX 500 mg/g powder for oral solution for pigs (AT, BE, FR, LU, NL)
STABOX 500 mg/g powder for oral solution for pigs (DK, ES, IE, IT, PT, UK/NI)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Amoxicillin (as trihydrate form) ..... 500.00 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium glycine carbonate
Colloidal anhydrous silica
Vanillin
Sodium hexametaphospate

White to almost white and slightly granular powder.

3. CLINICAL INFORMATION

3.1 Target species

Pig (weaned piglet).

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in cases of hypersensitivity to penicillins or other substances of the ß-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 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.

3.4 Special warnings

None.

3.5 Special precautions for use

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 SPC may increase the prevalence of bacteria resistant to amoxicillin.

Narrow spectrum antibacterial therapy should be used for first line treatment where susceptibility testing suggests 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pig (weaned piglet):

Undetermined frequency (cannot be estimated from the available data):	Hypersensitivity reaction[1] (e.g. allergic reaction[1])

[1] May be caused by penicillins and cephalosporins. May occasionally be serious.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

Pregnancy and lactation:

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.

3.8 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.

3.9 Administration routes and dosage

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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 14 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CA04

4.2 Pharmacodynamics

Amoxicillin is a semi-synthetic penicillin derived from the 6 APA core (6 amino-penicillic acid). It is a broad spectrum antibiotic, bactericidal against Gram-positive and Gram-negative bacteria, in particular *Actinobacillus pleuropneumoniae*, isolated in pigs.

Amoxicillin acts by inhibition of bacterial cell wall synthesis or activation of enzymes disrupting cell walls (bactericidal action).

4.3 Pharmacokinetics

In pigs, after the administration of the veterinary medicinal product at a dose of 20 mg/kg in liquid feed, amoxicillin maximal plasma concentration of 2.0 µg/ml is reached 1.8 hours after the administration. The repeated administration of the drug does not lead to accumulation. The average absolute bioavailability of amoxicillin in liquid feed is estimated to be 12 %.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 10 days.
Shelf life after dissolution in liquid feed: 2 hours.

5.3. Special precautions for storage

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

5.4 Nature and composition of immediate packaging

- Box with 50 g high density polyethylene jar hermetically closed by thermosealed aluminium polyethylene seal and over screw cap.
- Box with 100 g high density polyethylene jar hermetically closed by thermosealed aluminium polyethylene seal and over screw cap.
- 200 g high density polyethylene jar hermetically closed by thermosealed aluminium polyethylene seal and over screw cap.
- 500 and 1000 g high density polyethylene jars hermetically closed by thermosealed aluminium polyethylene seal and over screw cap.
- 1500 and 3000 g high density polyethylene barrels closed hermetically by screw caps equipped with an internal rubber seal and an external security compact seal.
- 500, 1000 and 2000 g multi-layer (low density polyethylene / aluminium / polyethyleneterephtalate) stand up pouches equipped with a zip.
- 3000 g multi-layer (low density polyethylene / aluminium / polyethyleneterephtalate) stand up pouches equipped with a zip and a handle.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

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

SURAMOX 500 mg/g powder for oral solution (AT, BE, FR, LU, NL)
STABOX 500 mg/g powder for oral solution (DK, ES, IE, IT, PT, UK/NI)

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

15. BATCH NUMBER

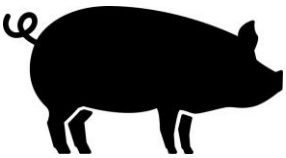
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Jar of 50 g or 100 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SURAMOX (AT, BE, FR, LU, NL)
STABOX (DK, ES, IE, IT, PT, UK/NI)



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

SURAMOX 500 mg/g powder for oral solution for pigs (AT, BE, FR, LU, NL)
STABOX 500 mg/g powder for oral solution for pigs (DK, ES, IE, IT, PT, UK/NI)

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 ß-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 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. 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[1] (e.g. allergic reaction[1])

[1] 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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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

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. Date on wich the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Manufacturer responsible for batch release:

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

Local representatives and contact details to report suspected adverse reactions:

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

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

SURAMOX 500 mg/g powder for oral solution for pigs (AT, BE, FR, LU, NL)
STABOX 500 mg/g powder for oral solution for pigs (DK, ES, IE, IT, PT, UK/NI)

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 ß-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 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.

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[1] (e.g. allergic reaction[1])

[1] 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 or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system: {national system details}.

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

Pack sizes

500, 1000, 2000 and 3000 g pouches.

Not all pack sizes may be marketed.

16. DATE ON WICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Manufacturer responsible for batch release:

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

Local representatives and contact details to report suspected adverse reactions:

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

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}