

ANNEX I

**LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS, ANIMAL SPECIES,
FREQUENCY AND ROUTES OF ADMINISTRATION, RECOMMENDED DOSES,
WITHDRAWAL PERIODS AND MARKETING AUTHORISATION HOLDERS IN THE
MEMBER STATES CONCERNED BY THE REFERRAL**

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period (meat and milk)
Czech Republic	Virbac S.A. Iere Avenue 2056 M Lid 06516 Carros Cedex France	Suramox 15% LA	Suspension for injection	150 mg/ml	Cattle, pigs	Two intramuscular injections at 48 hours interval	15 mg amoxicillin/kg bw (equivalent to 1ml/10 kg)	Meat and offal: Cattle: 58 days Pigs: 35 days Milk: 2.5 days
Spain ¹	Virbac S.A. Iere Avenue 2056 M Lid 06516 Carros Cedex France	Stabox 15% LA	Suspension for injection	150 mg/ml	Cattle, pigs	Two intramuscular injections at 48 hours interval	15 mg amoxicillin/kg bw (equivalent to 1ml/10 kg)	Meat and offal: Cattle: 58 days Pigs: 35 days Milk: 2.5 days
Italy	Virbac S.A. Iere Avenue 2056 M Lid 06516 Carros Cedex France	Stabox 15% LA	Suspension for injection	150 mg/ml	Cattle, pigs	Two intramuscular injections at 48 hours interval	15 mg amoxicillin/kg bw (equivalent to 1ml/10 kg)	Meat and offal: Cattle: 58 days Pigs: 35 days Milk: 2.5 days
France ²	Virbac S.A. Iere Avenue 2056 M Lid 06516 Carros Cedex France	Suramox 15% LA	Suspension for injection	150 mg/ml	Cattle, pigs	Two intramuscular injections at 48 hours interval	15 mg amoxicillin/kg bw (equivalent to 1ml/10 kg)	Meat and offal: Cattle: 58 days Pigs: 35 days Milk: 2.5 days

¹ Marketing Authorisation not granted

² Reference Member State for the Mutual recognition Procedure

ANNEX II
SCIENTIFIC CONCLUSIONS

SCIENTIFIC CONCLUSIONS

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF RESIDUE DATA FOR SURAMOX 15% LA AND ITS ASSOCIATED NAME STABOX 15% LA, SUBMITTED TO THE CVMP AS A FOLLOW-UP OF AN ARTICLE 35 REFERRAL, FOR LIFTING THE SUSPENSION OF THE MARKETING AUTHORISATIONS

1. Introduction

Suramox 15% LA and its associated name Stabox 15% LA is presented as an injectable suspension containing amoxicillin, which is a β -lactam antibiotic, belonging to the group of penicillins intended for the treatment of respiratory infections caused by *Pasteurella multocida* and *Mannheimia haemolytica* in cattle and for the treatment of respiratory infections due to *Pasteurella multocida* in pigs. In both species the product is administered intramuscularly at a dose rate of 15 mg amoxicillin/kg bw (equivalent to 1 ml of Suramox 15% LA/10 kg bw) twice at 48 hours interval.

Amoxicillin was previously evaluated by the CVMP together with other penicillins, in order to establish maximum residue limits (MRLs). However, an ADI for penicillins was not established.

Benzylpenicillin was considered by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 36th meeting in 1990. Several cases of allergic reactions in humans following the ingestion of food containing penicillin residues were reviewed. Reports of further cases, which were not available to JECFA, had also been reported in the published literature. It was evident that penicillin residues have caused allergic reactions in consumers and that some of these reactions have been serious. Being aware of cases of allergic reactions at very low doses, JECFA recommended that the daily intake of benzylpenicillin from food be kept as low as practicable, and in any case below 30 μ g parent drug per person.

In setting maximum residue limits (MRLs) for the penicillins, the CVMP adopted the same approach as the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The CVMP set MRLs such that consumer intake from all foods would not exceed this 30 μ g threshold.

On this basis MRLs for amoxicillin and other penicillins were proposed by the CVMP, and amoxicillin is currently entered in Annex I of Council Regulation (EEC) No 2377/90, in accordance with the following table:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissue	Other provisions
Amoxicillin	Amoxicillin	All food producing species	50 μ g/kg 50 μ g/kg 50 μ g/kg 50 μ g/kg 4 μ g/kg	Muscle Fat Liver Kidney Milk	

2. Assessment of residue depletion studies

In order to obtain the lifting of the suspension of the marketing authorisations for Suramox 15% LA and its associated name Stabox 15% LA, the marketing authorisation holder performed four new residue studies in cattle and five new residue studies in pigs.

2.1 Residue studies in cattle

The first residue depletion study in cattle was performed to identify the time points to be used in the pivotal residue depletion study. The results from the study were used to design the pivotal residue study to include time points at 7, 14, 46 and 57 days after the last injection.

In the pivotal residue study, heavy animals (body weight: 600 to 692 kg) were used (eight males and eight females). The animals were given 15 mg amoxicillin/kg bw corresponding to 1ml/10 kg bw which required 4 injections, three of which were the maximum volumes (20 ml) and the remaining given in the fourth injection. The dosage was repeated 48 hours later. The animals were slaughtered at 7, 14, 46 and 57 days after the final injection. All samples were analysed for amoxicillin concentrations using a validated HPLC-MS/MS method with a limit of quantification of 25 µg/kg for all tissues. Residue levels in fat, liver, kidney and non-injection site muscle were below the limit of quantification from the first time point (7 days) with the exception of one kidney sample that contained residues at the level of the limit of quantification (25 µg/kg). At the injection site, residues above the muscle MRLs were found in all three core samples at the last time point tested (57 days) and as a result two other residues studies measuring residue levels at 80 and 90 days were carried out.

In the complementary studies animals that were younger and weighed much less (211 to 249; 206 to 228 kg) were used; otherwise the studies were conducted similarly to the pivotal study. In view of the weight of the animals only one injection site sample (core plus surrounding) was available for analysis unlike in the pivotal study where there were three samples per animal. The use of heavier animals would have given extra assurance about residues levels at the injection site and would have made all studies homogenous. However, there are data to show residue depletion from at least one injection site which received the maximum volume and therefore the studies could be accepted for the purposes of setting the meat withdrawal period in cattle.

Residues from the core injection site and its surrounding also remained below the limit of detection of muscle (2.1 µg/kg) in all samples after 80 days and three samples after 90 days with remaining one being below the limit of quantification (25 µg/kg).

2.2 Determination of meat withdrawal periods for cattle

Residue levels in kidney, fat, liver and non-injection site muscle were below their respective MRLs from the first time point (7 days) tested. Using the 'alternative approach' as stated in CVMP Note for guidance on the approach towards harmonisation of withdrawal periods (EMEA/CVMP/036/95) a withdrawal period of 8 days is obtained after adding 10 % 'uncertainty factor'.

However, the actual withdrawal period for the product is to be based on the injection site residues.

The statistical approach, although preferred, could not be used for the calculation of the withdrawal period at the injection site given the non homogeneous nature of the studies as shown by the weight differences as well as the way residue levels were determined (3 samples versus just one), and therefore the 'alternative approach' as set out in the CVMP Note for guidance on the approach towards harmonisation of withdrawal periods (EMEA/CVMP/036/95) was used. The first time point where residues fell below their respective MRLs was 80 days in all injection site samples. Considering that there is data at an additional time point (90 days) where residues were below the limit of quantification the addition of a 10 % 'uncertainty factor' was accepted. A withdrawal period of 88 days is therefore established for cattle.

2.3 Residue studies in pigs

The pilot residue depletion study in pigs was performed to identify the time points to be used in the pivotal residue depletion study. The results from the study were used to design the pivotal residue study to include time points at 7, 14, 21 and 27 days after the last injection.

In the pivotal residue study, heavy animals (body weight: 66 - 84.5 kg) were used (eight male and eight female). The animals were given 15 mg amoxicillin/kg bw corresponding to 1ml/10 kg/bw which required 2 injections, one of which was the maximum volume (5 ml) and the remaining given in the second injection. The dosage was repeated 48 hours later. Animals (2 male and 2 female) were slaughtered at 7, 14, 21 and 27 days after the final injection. All samples were analysed for amoxicillin concentrations using a validated HPLC-MS/MS method with a limit of quantification of 25 µg/kg for all tissues. Residue levels in fat+skin, liver and non injection site muscle were all below the limit of quantification from the first time point (7 days) with the exception of one kidney sample which had residues above the MRL at the first time point and another one above the Limit of quantification. The other two kidney samples were below the limit of quantification (25 µg/kg). At the injection site residues above the muscle MRLs were found in at least one core sample at the last time point tested (27 days) and as a result three other residues studies measuring residue levels at 30, 36, 38 and 46 days were carried out.

The three complementary studies were conducted similarly to the pivotal study but in one of the complementary studies animals were younger and weighing much less (53 to 59 kg) than the ones used in the other studies were used but they did all receive at least the maximum injection volume (5 ml). With the exception of one animal after 36 days which had high residues (core sample 339.4 µg/kg), residue levels were below the MRL after 30, 38 and 46 days.

2.4 Determination of meat withdrawal periods for pigs

Residue levels in skin+fat, liver and non-injection site muscle were below their respective MRLs from the first time point (7 days) tested and for kidneys from the second time point (14 days). Using the 'alternative approach' as stated in CVMP Note for guidance on the approach towards harmonisation of withdrawal periods (EMEA/CVMP/036/95) a withdrawal period of 16 days is obtained after adding 10 % 'uncertainty factor'.

However, the actual withdrawal period for the product is to be based on the injection site residues.

The statistical approach could not be used for the calculation of the withdrawal period as the test for log-linearity (F-test) was not met and therefore the 'alternative approach' as set out in the CVMP guideline (EMEA/CVMP/036/95-Final) was used. The first time point where residues fell below their respective MRLs was 38 days in all injection site samples. A safety span of 30% was considered necessary in this case because at the previous time point, which was only 2 days earlier, one sample contained residues of nearly 7 times the MRL. This leads to a withdrawal period of 50 days. Further reassurance as to the adequacy of this withdrawal period is provided by the fact that at 46 days residues were below the LOQ in all injection site samples. A withdrawal period of 50 days is therefore established for pigs.

3. Conclusions and recommendations

Having considered the new residue depletion data provided for the lifting of the suspension of the marketing authorisations for Suramox 15% LA and its associated name Stabox 15% LA concerning the establishment of withdrawal periods for cattle and pigs, the CVMP concluded that:

- the new residue depletion studies in both cattle and pigs are of an acceptable standard and in large part in accordance with CVMP guideline on injection site residues (EMEA/CVMP/542/03);
- time points where residues at the injection sites were below the muscle MRL were identified for both cattle and pigs;
- A meat withdrawal period can be set in both cattle and pigs using the 'Alternative approach' as stated in the CVMP Note for guidance on the approach towards harmonisation of withdrawal periods (EMEA/CVMP/036/95);
- A meat withdrawal period of 88 days for cattle and 50 days for pigs can now be established;

Therefore, the Committee for Medicinal Products for Veterinary Use recommends to lift the suspension of the marketing authorisations for Suramox 15% LA and its associated name Stabox 15% LA and to vary the marketing authorisations in order to set the withdrawal periods as stated above.

ANNEX III
SUMMARY OF PRODUCT CHARACTERISTICS,
LABELLING AND PACKAGE LEAFLET

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suramox 15% LA, suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Micronised amoxicillin (as trihydrate)	150.0 mg
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Excipient:

Benzyl alcohol	35.0 mg
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For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and pigs

4.2 Indications for use, specifying the target species

Cattle: Treatment of respiratory infections due to *Pasteurella multocida* and *Mannheimia haemolytica*.

Pigs: Treatment of respiratory infections due to *Pasteurella multocida*.

4.3 Contraindications

Do not use in animals with known hypersensitivity to penicillin or other substances of the β -lactam group.

Do not use in rabbits, guinea pigs, hamsters or gerbils.

Do not use in case of known resistance to amoxicillin.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Shake well before use.

Strict aseptic precautions should be observed.

In case of the occurrence of allergic reaction, the treatment should be immediately withdrawn.

In animals with hepatic and renal failure, the dosage regimen should be carefully evaluated.

Inappropriate use of the product may increase the prevalence of bacteria resistant to amoxicillin.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

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 product if you know you are sensitised, or if you have been advised not to work with such preparations.

In case of accidental contact with eyes, rinse immediately with copious amounts of water.

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.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions unrelated to dose can be observed. Allergic reactions, skin reactions, anaphylaxis) may occur.

4.7 Use during pregnancy, lactation or lay

Studies performed in laboratory animals (rat, rabbit), did not show a teratogenic, embryotoxic or maternotoxic effect of amoxicillin. The safety of the product has not been assessed in pregnant and lactating targets species. Use in such cases only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

The bactericidal effect of amoxicillin is neutralised by simultaneous use of bacteriostatic acting pharmaceuticals (macrolides, sulphonamides and tetracyclines).

4.9 Amounts to be administered and administration route

Intramuscular injection (cattle, pigs).

Cattle and pigs: Administer 15 mg amoxicillin (as trihydrate) per kg bodyweight equivalent to 1 ml per 10 kg, twice at 48 hours interval.

Shake well before use.

It is recommended that the maximum volume administered per site of injection should not exceed 20 ml in cattle and 5 ml in swine.

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

No information is available.

4.11 Withdrawal period(s)

Meat and offal:

- Cattle: 88 days
- Pigs: 50 days

- Milk: 2.5 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Penicillins with extended spectrum

ATCVet code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin belongs to β -lactams antibiotic family. Its structure contains the β -lactam ring and thiazolidine ring common to all penicillins. Amoxicillin is active against susceptible Gram positive and Gram negative bacteria.

β -lactam antibiotics prevent the bacterial cell wall synthesis by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes which catalyse cross-linkage of the glycopeptide polymer units that form the cell wall. They exert a bactericidal action on growing cells only.

Amoxicillin is susceptible to breakdown by β -lactamases produced by some bacterial strains.

Another possible mode of resistance to β -lactam antibiotics can be associated with chromosomal mutations in bacteria resulting either in modification of the penicillin binding proteins (PBPs) or in modification of the cellular permeability to β -lactams. By their nature such chromosomal mutations tend to be relatively slow in developing and occur primarily by vertical transmission. *Escherichia coli* resistance has been reported.

5.2 Pharmacokinetic particulars

After intramuscular administration amoxicillin is well absorbed and distributed in the tissues.

After a single intramuscular administration of the product at 15 mg/kg to pigs, mean amoxicillin plasma peak concentration of 3.78 μ g/ml is reached 0.77 hours after dosing. The mean half-life of elimination is 7 hours.

After a single intramuscular administration of the product at 15 mg/kg to cattle, mean amoxicillin plasma peak concentration of 2.93 μ g/ml is reached 1.64 hours after dosing. The mean half-life of elimination is 12 hours.

The main elimination route of amoxicillin is via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Stearic acid
Aluminium stearate
Propylene glycol dicaprylate/dicaprate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months.

Shelf-life after first opening the container: 28 days.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Polyethylene terephthalate (PET) bottles with rubber closures and aluminium capsules

Product presentations:

Box of 125 ml bottle

Box of 250 ml bottle

Box of 500 ml bottle

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

VIRBAC S.A.

1ère Avenue - 2065 m - L.I.D.

06516 CARROS CEDEX

FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<{DD/MM/YYYY}> <{DD month YYYY}>

10 DATE OF REVISION OF THE TEXT

{MM/YYYY} or <month YYYY>

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX of 125, 250 or 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suramox 15% LA, suspension for injection
Amoxicillin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Micronised amoxicillin (as trihydrate) 150.0 mg/ml
Excipient: Benzyl alcohol 35.0 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

Box of 125 ml bottle
Box of 250 ml bottle
Box of 500 ml bottle

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

Cattle: Treatment of respiratory infections due to *Pasteurella multocida* and *Mannheimia haemolytica*.

Pigs: Treatment of respiratory infections due to *Pasteurella multocida*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Intramuscular injection (cattle, pigs).

Cattle and pigs: Administer 15 mg amoxicillin (as trihydrate) per kg bodyweight equivalent to 1 ml per 10 kg, twice at 48 hours interval.

Shake well before use.

It is recommended that the maximum volume administered per site of injection should not exceed 20 ml in cattle and 5 ml in swine.

8. WITHDRAWAL PERIOD

Meat and offal:

- Cattle: 88 days

- Pigs: 50 days

- Milk: 2.5 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental injection is dangerous – see package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>
Shelf-life after first opening the container: 28 days

11. SPECIAL STORAGE CONDITIONS

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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 S.A.
1ère Avenue - 2065 m - L.I.D.
06516 CARROS CEDEX
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER'S BATCH NUMBER**

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 125, 250 or 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suramox 15% LA, suspension for injection
Amoxicillin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Micronised amoxicillin (as trihydrate) 150.0 mg/ml

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

Bottle of 125, 250 or 500 ml.

4. TARGET SPECIES

Cattle and pigs

5. INDICATION(S)

Cattle: Treatment of respiratory infections due to *Pasteurella multocida* and *Mannheimia haemolytica*.

Pigs: Treatment of respiratory infections due to *Pasteurella multocida*.

6. ROUTE(S) OF ADMINISTRATION

Intramuscular injection

7. WITHDRAWAL PERIOD

Meat and offal:

- Cattle: 88 days
- Pigs: 50 days

- Milk: 2.5 days

8. BATCH NUMBER

<Batch> <Lot> <BN> {number}

9. EXPIRY DATE

<EXP {month/year}>

Shelf-life after first opening the container: 28 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

9. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC S.A.
1ère Avenue - 2065 m - L.I.D.
06516 CARROS CEDEX
FRANCE

10. MARKETING AUTHORISATION NUMBER(S)

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Suramox 15% LA, suspension for injection

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

VIRBAC S.A.
1ère Avenue - 2065 m - L.I.D.
06516 CARROS CEDEX
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suramox 15% LA, suspension for injection
Amoxicillin

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

Micronised amoxicillin (as trihydrate) 150.0 mg/ml
Excipient: Benzyl alcohol 35.0 mg/ml

4. INDICATION(S)

Cattle: Treatment of respiratory infections due to *Pasteurella multocida* and *Mannheimia haemolytica*.

Pigs: Treatment of respiratory infections due to *Pasteurella multocida*.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to penicillin or other substances of the β -lactam group.

Do not use in rabbits, guinea pigs, hamsters or gerbils.
Do not use in case of known resistance to amoxicillin

6. ADVERSE REACTIONS

Hypersensitivity reactions unrelated to dose can be observed. Allergic reactions, skin reactions, anaphylaxis) may occur.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and pigs

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

Intramuscular injection (cattle, pigs).

Cattle and pigs: Administer 15 mg amoxicillin (as trihydrate) per kg bodyweight equivalent to 1 ml per 10 kg, twice at 48 hours interval.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

It is recommended that the maximum volume administered per site of injection should not exceed 20 ml in cattle and 5 ml in swine.

10. WITHDRAWAL PERIOD

Meat and offal:

- Cattle: 88 days

- Pigs: 50 days

- Milk: 2.5 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 required.

Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Shake well before use.

Strict aseptic precautions should be observed.

In case of the occurrence of allergic reaction, the treatment should be immediately withdrawn.

In animals with hepatic and renal failure, the dosage regimen should be carefully evaluated.

Inappropriate use of the product may increase the prevalence of bacteria resistant to amoxicillin.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

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 product if you know you are sensitised, or if you have been advised not to work with such preparations.

In case of accidental contact with eyes, rinse immediately with copious amounts of water.

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 during pregnancy or lactation

Studies performed in laboratory animals (rat, rabbit), did not show a teratogenic, embryotoxic or maternotoxic effect of amoxicillin. The safety of the product has not been assessed in pregnant and lactating targets species. Use in such cases 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 neutralised by simultaneous use of bacteriostatic acting pharmaceuticals (macrolides, sulphonamides and tetracyclines).

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Not all pack sizes may be marketed.