ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SYNULOX PALATABLE DROPS 40 mg/ml + 10 mg/ml, Powder for Oral Suspension – Northern Ireland
SYNULOX GOUTTES APPÉTENTES, Poudre pour suspension orale – Belgium and Luxemburg
SYNULOX GOUTTES – France
SYNULOX VET 40 MG/ML JAUHE ORAALISUSPENSIOTA VARTEN – Finland
SYNULOX PULVER 40/10 MG/ML PULVER ZUR HERST. EINER SUSP. FÜR HUNDE UND KATZEN – Germany
SYNULOX PALATABLE DROPS 750 MG – Italy
SYNULOX SMAKELIJKE DRUPPELS – The Netherlands
SYNULOX POLVO PARA GOTAS ORALES EN SUSPENSION – Spain

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each bottle of powder contains:
648 mg amoxicillin (equivalent to 743,8 mg amoxicillin trihydrate)
162 mg clavulanic acid (equivalent to 193 mg potassium clavulanate)

Each ml of reconstituted oral suspension contains:
Amoxicillin 40 mg
Clavulanic acid 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Xanthan gum
Saccharin sodium
Succinic acid
Silica colloidal anhydrous
Silicon dioxide (Silica gel)
Strawberry dry flavour
Peach dry flavour
Lemon dry flavour

Powder: Off-white powder.
After reconstitution: Off-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Dogs:
For the treatment of
- Skin infections (including deep and superficial pyoderma).

- Soft tissue infections (including anal sacculitis and abscesses).
- Urinary tract infections.
- Respiratory infections.
- Intestinal infections.
- Periodontal infections in addition to mechanical or surgical periodontal therapy.

Cats:
For the treatment of
- Skin infections (including superficial pyoderma).
- Soft tissue infections (including abscesses).
- Urinary tract infections.
- Respiratory infections.
- Intestinal infections.
- Periodontal infections in addition to mechanical or surgical periodontal therapy.

3.3 Contraindications

Do not use in rabbits, guinea pigs, hamsters, gerbils, chinchillas or other small herbivores.

Do not use in cases of hypersensitivity to the active substances, other substances of the beta-lactam group or to any of the excipients.

Do not administer to horses or ruminating animals.

Do not use in animals with severe renal impairment with anuria or oliguria.

3.4 Special warnings

Cross-resistance has been shown between amoxicillin/clavulanic acid and other antibiotics belonging to the beta-lactam group. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to other antimicrobials in the beta-lactam group because its effectiveness may be reduced.
When susceptibility testing has shown resistance to sole beta-lactam, but susceptibility to combination of amoxicillin/clavulanic acid has been confirmed, treatment with the veterinary medicinal product might nevertheless be considered.

Do not use in cases of suspected or confirmed methicillin resistant *S. aureus* (MRSA) and methicillin resistant *S. pseudintermedius* (MRSP) infections, as such isolates should be considered resistant to all beta-lactams including amoxicillin/clavulanic acid combinations.

The veterinary medicinal product has no effect against infections caused by *Pseudomonas* spp. due to its inherent resistance.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

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

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Pharmacokinetic of the active substances in the target tissue might be considered as well.

The routine use of systemic antibiotics for intestinal infections is not recommended.

Oral treatment with antibiotics can result in disturbance of gastrointestinal flora, especially in case of long-term treatment.

In case of renal or hepatic insufficiency, the use of the veterinary medicinal product should be subject to a benefit-risk assessment by the responsible veterinarian.

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 can lead to cross-reactions with cephalosporins and vice versa. Allergic reactions caused by these substances may occasionally be serious.

People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product. Wear gloves when handling this product to avoid skin contact.

In case of accidental spillage onto skin or eyes immediately wash the affected area with plenty of water.

If you develop symptoms such as a skin rash and persistent eye irritation after exposure to the veterinary medicinal product, seek medical advice immediately and show the package leaflet or label to the physician. Swelling of the face, lips, or eyes, or difficulty breathing are more serious symptoms that require urgent medical attention.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Common (1 to 10 animals / 100 animals treated):	gastrointestinal disorder[1] (e.g. vomiting, diarrhoea)
Uncommon (1 to 10 animals / 1 000 animals treated):	hypersalivation anorexia[1, 2], lethargy
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	hypersensitivity reaction[3] (e.g. allergic skin reaction, anaphylaxis)

[1] Depending on the severity of the adverse event treatment should be discontinued and symptomatic treatment initiated based on the benefit-risk assessment by the responsible veterinarian.
[2] Very rare (<1 animal / 10 000 animals treated, including isolated reports) in cats.
[3] May be serious. Immediate discontinuation of the veterinary medicinal product is required. Countermeasures to be taken in case of an allergic reaction:

- anaphylaxis: administer epinephrine (adrenaline) and glucocorticoids.
- allergic skin reactions: administer antihistamines and/or glucocorticoids.

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.

Pregnancy and lactation:
In laboratory studies (rat, mouse), signs of embryotoxicity or teratogenicity could only be detected at high doses.
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 may be inhibited by the concomitant use of bacteriostatic antimicrobials.

Penicillins may increase the effect of aminoglycosides.

3.9 Administration routes and dosage

Oral use.

Dosage: 10 mg amoxicillin and 2.5 mg clavulanic acid/kg body weight every 12 hours equivalent to 0.25 ml reconstituted product/kg body weight every 12 hours or 5 drops per kg body weight every 12 hours.

In refractory respiratory tract infections, the dose can be doubled to 20 mg amoxicillin and 5 mg clavulanic acid/kg body weight every 12 hours and the treatment can be prolonged for up to 10 days.

Dosing instructions:

Body weight (kg)	**Quantity (ml) of reconstituted veterinary medicinal product every 12 hours per dose level**	
	10 mg amoxicillin and 2.5 mg clavulanic acid/kg	**20 mg amoxicillin and 5 mg clavulanic acid/kg**
0.5 – 1	0.15 (3 drops*) to 0.25 (5 drops)	0.30 (6 drops) to 0.5 (10 drops)
>1 – 2	0.3 (6 drops) to 0.5 (10 drops)	0.6 (12 drops) to 1 (20 drops)
>2 – 3	0.55 (11 drops) to 0.75 (15 drops)	1.1 (22 drops) to 1.5 (30 drops)
>3 – 4	0.8 (16 drops) to 1 (20 drops)	1.6 (32 drops) to 2 (40 drops)

*1 drop delivers approximately 0.05 ml of the suspension.

Duration of treatment:
In most of the cases, a treatment duration of 5 to 7 days is sufficient.
For chronic cases, a longer course of therapy may be required.
Based on clinical trials, the following treatment durations are recommended:
Chronic skin infections, 10–20 days.
Chronic cystitis, 10–28 days.

Instructions for use:
To ensure a correct dosage, body weight should be determined as accurately as possible.

Open the bottle. Discard the original aluminium cap. Reconstitute the powder with 15 ml of tap water. Close the bottle with the dropper cap and shake vigorously to obtain a milky suspension. Open the bottle and use the dropper (graduated from 0.25 to 1 ml) to extract the prescribed amount. If needed, gently squeeze the rubber portion of the dropper to drop the excess of the veterinary medicinal product back into the bottle.

Administer the veterinary medicinal product with the graduated dropper either directly into the animal's mouth or mixed with some food.

Shake the veterinary medicinal product well before each use.

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

Doses up to 40 mg amoxicillin and 10 mg clavulanic acid/kg and 60 mg amoxicillin and 15 mg clavulanic acid/kg administered twice daily for 5 days were tolerated well in young dogs and young cats respectively.
No adverse events associated with overdoses other than those listed in section 3.6 were detected in the respective studies (for information on symptomatic treatment see also section on adverse events).

Due to the neurotoxicity of penicillins, overdosing might result in central nervous system symptoms and convulsions. In these cases, treatment with the veterinary medicinal product should be discontinued immediately and symptomatic treatment should be initiated.

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

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CR02

4.2 Pharmacodynamics

The veterinary medicinal product is an association of amoxicillin and clavulanic acid. Amoxicillin inhibits the cross-linking of the peptidoglycan layer through a selective and irreversible blockage of various enzymes involved in this process (primarily transpeptidases) and thus prevents the formation of an intact bacterial cell wall. This results in an osmotic imbalance that particularly affects bacteria in the logarithmic phase of growth which ultimately leads to bacterial cell lysis. The effect is therefore bactericidal and related to the time the susceptible organisms are exposed to supra-minimum inhibitory concentrations. Clavulanic acid has a similar structure to beta-lactam antibiotics such as amoxicillin. It has a weak antibacterial effect but, compared to amoxicillin, has a higher affinity for beta-lactamases, enzymes produced by Gram-positive and Gram-negative bacteria which inactivate beta-lactam antibiotics through the hydrolytic cleavage of their beta-lactam ring. When administered simultaneously with amoxicillin, clavulanic acid rapidly, progressively and irreversibly inactivates the beta-lactamases by forming a stable molecule-enzyme complex. This prevents inactivation of amoxicillin by beta-lactamases and, as a result, the spectrum of amoxicillin is broadened to include

strains that have acquired resistance through secretion of plasmid-derived penicillinase, and strains that are naturally resistant through the production of chromosomally mediated beta-lactamases. Other mechanisms of resistance to beta-lactams include the modification of the antibiotic target site (penicillin-binding proteins), efflux pumps and changes in the permeability of the outer membrane.

4.3 Pharmacokinetics

Following oral administration, amoxicillin is well absorbed from the gastrointestinal tract. In dogs, bioavailability is 60-70%. Following absorption, the highest concentrations are found in the kidneys (urine), bile and further in the liver, lungs, heart, and spleen.
Distribution of amoxicillin to the cerebrospinal fluid is low unless meningitis occurs.
Amoxicillin is excreted mainly by the kidneys (unchanged in the urine).
Clavulanic acid is well absorbed after oral administration and has pharmacokinetic properties similar to amoxicillin. Extracellular distribution of clavulanic acid is extensive, but permeation into milk and cerebrospinal fluid is very limited. Clavulanic acid is excreted unchanged by the kidneys.

Dogs
Several studies involving 54 dogs administered the veterinary medicinal product at a dose of 10 mg amoxicillin and 2.5 mg clavulanic acid per kg of body weight showed the following results:

- For amoxicillin, the time to reach maximum concentration (T_{max}) ranged from 1 to 2 hours, with a maximum concentration (C_{max}) between 4.6 and 8.4 mcg/ml. The mean elimination half-life ($T_{½}$) was between 0.85 and 1.42 hours.
- For clavulanic acid, the C_{max} ranged from 0.32 to 2 mcg/ml, the T_{max} from 0.5 to 2 hours, and the $T_{½}$ from 0.59 to 0.8 hours.

Cats
Studies involving cats administered the veterinary medicinal product at a dose of 10 mg amoxicillin and 2.5 mg clavulanic acid/kg body weight showed the following results:

- For amoxicillin, the T_{max} was 2 hours with a C_{max} between 4.5 and 7.43 mcg/ml. The $T_{½}$ was between 0.97 and 1.44 hours.
- For clavulanic acid, the T_{max} was 1 hour with a C_{max} ranging from 1.52 to 2.3 mcg/ml. The $T_{½}$ ranged from 0.5 to 0.9 hours.

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 reconstitution according to directions: 7 days.

5.3 Special precautions for storage

Do not store above 25°C.
Store the reconstituted veterinary medicinal product in a refrigerator (2°C - 8°C).

5.4 Nature and composition of immediate packaging

Ph. Eur. Type III clear glass bottle with nominal volume of 15 ml, closed with a metal screw cap fitted with a grey liner with a wrinkled surface composed of a chlorobutyl based compound. A dropper with graduations of 0.25 ml up to 1 ml is included. The dropper is manufactured from low density polyethylene and contains no additives.

Pack sizes: Cardboard box containing 1 x 15 ml bottle and 1 x graduated dropper.

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

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

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SYNULOX PULVER 40/10 MG/ML PULVER ZUR HERST. EINER SUSP. FÜR HUNDE UND KATZEN – Germany

2. STATEMENT OF ACTIVE SUBSTANCES

After reconstitution, each ml contains:
Amoxicillin 40 mg
Clavulanic acid 10 mg

3. PACKAGE SIZE

1 x 15 ml after reconstitution

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Reconstitute with 15 ml water.
Shake well before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 7 days.
Use by…

9. SPECIAL STORAGE PRECAUTIONS

Powder: Do not store above 25°C.
Suspension: Store in a refrigerator

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SYNULOX PULVER 40/10 MG/ML PULVER ZUR HERST. EINER SUSP. FÜR HUNDE UND KATZEN – Germany

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

After reconstitution, each ml contains:
Amoxicillin 40 mg
Clavulanic acid 10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 7 days.
Use by…

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

SYNULOX PULVER 40/10 MG/ML PULVER ZUR HERST. EINER SUSP. FÜR HUNDE UND KATZEN – Germany

2. Composition

Active substance:
Each bottle of powder contains:
648 mg amoxicillin (equivalent to 743,8 mg amoxicillin trihydrate).
162 mg clavulanic acid (equivalent to 193 mg potassium clavulanate)

Each ml of reconstituted oral suspension contains:

Amoxicillin	40 mg
Clavulanic acid	10 mg

Powder: Off-white.
After reconstitution: Off-white suspension.

3. Target species

Dogs and cats.

4. Indications for use

Dogs:
For the treatment of
- Skin infections (including deep and superficial pyoderma).
- Soft tissue infections (including anal sacculitis and abscesses).
- Urinary tract infections.
- Respiratory infections.
- Intestinal infections.
- Periodontal infections (infections of the tissues surrounding the teeth) in addition to mechanical or surgical periodontal therapy.

Cats:
For the treatment of
- Skin infections (including superficial pyoderma).
- Soft tissue infections (including abscesses).
- Urinary tract infections.
- Respiratory infections.
- Intestinal infections.
- Periodontal infections (infections of the tissues surrounding the teeth) in addition to mechanical or surgical periodontal therapy.

5. Contraindications

Do not use in rabbits, guinea pigs, hamsters, gerbils, chinchillas or other small herbivores.

Do not use in cases of hypersensitivity to the active substances, other substances of the beta-lactam group or to any of the excipients.

Do not administer to horses or ruminating animals.

Do not use in animals with severe renal impairment with no or decreased urine production (anuria or oliguria).

6. Special warnings

Special warnings:
Cross-resistance has been shown between amoxicillin/clavulanic acid and other antibiotics belonging to the beta-lactam group. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to other antimicrobials in the beta-lactam group because its effectiveness may be reduced.
When susceptibility testing has shown resistance to sole beta-lactam, but susceptibility to combination of amoxicillin/clavulanic acid has been confirmed, treatment with the veterinary medicinal product might nevertheless be considered.

Do not use in cases of suspected or confirmed methicillin resistant *S. aureus* (MRSA) and methicillin resistant *S. pseudintermedius* (MRSP) infections, as such isolates should be considered resistant to all beta-lactams including amoxicillin/clavulanic acid combinations.

The veterinary medicinal product has no effect against infections caused by *Pseudomonas* spp. due to its inherent resistance.

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

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

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Pharmacokinetic of the active substances in the target tissue might be considered as well.

The routine use of systemic antibiotics for intestinal infections is not recommended.

Oral treatment with antibiotics can result in disturbance of gastrointestinal flora, especially in case of long-term treatment.

In case of renal or hepatic insufficiency, the use of the veterinary medicinal product should be subject to a benefit-risk assessment by the responsible veterinarian.

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 can lead to cross-reactions with cephalosporins and vice versa. Allergic reactions caused by these substances may occasionally be serious.

People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product. Wear gloves when handling this product to avoid skin contact.

In case of accidental spillage onto skin or eyes, immediately wash the affected area with plenty of water.

If you develop symptoms such as a skin rash and persistent eye irritation after exposure to the veterinary medicinal product, seek medical advice immediately and show the package leaflet or label to the physician. Swelling of the face, lips, or eyes, or difficulty breathing are more serious symptoms that require urgent medical attention.

Wash hands after use.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
In laboratory studies (rat, mouse), signs of embryotoxicity or teratogenicity could only be detected at high doses.
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 may be inhibited by the concomitant use of bacteriostatic antimicrobials.
Penicillins may increase the effect of aminoglycosides.

Overdose:
Doses up to 40 mg amoxicillin and 10 mg clavulanic acid/kg and 60 mg amoxicillin and 15 mg clavulanic acid/kg administered twice daily for 5 days were tolerated well in young dogs and young cats respectively.
No adverse events associated with overdoses other than those listed in section 'Adverse events' were detected in the respective studies (for information on symptomatic treatment see also section on adverse events).
Due to the toxic effect of penicillins on the nervous system, overdosing might result in central nervous system symptoms and convulsions. In these cases, treatment with the veterinary medicinal product should be discontinued immediately and symptomatic treatment should be initiated.

<Special restrictions for use and special conditions for use:>

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

7. Adverse events

Dogs and cats:

Common (1 to 10 animals / 100 animals treated):
gastrointestinal disorder[1] (e.g. vomiting, diarrhoea)
Uncommon (1 to 10 animals / 1 000 animals treated):
hypersalivation anorexia[1, 2], lethargy
Very rare (<1 animal / 10 000 animals treated, including isolated reports):
hypersensitivity reaction[3] (e.g. allergic skin reaction, anaphylaxis)

[1] Depending on the severity of the adverse event treatment should be discontinued and symptomatic treatment initiated based on the benefit-risk assessment by the responsible veterinarian.
[2] Very rare (<1 animal / 10 000 animals treated, including isolated reports) in cats.

[3] May be serious. Immediate discontinuation of the veterinary medicinal product is required.
Countermeasures to be taken by the veterinarian in case of an allergic reaction:
- anaphylaxis: administer epinephrine (adrenaline) and glucocorticoids.
- allergic skin reactions: administer antihistamines and/or glucocorticoids.

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 its local representative> 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.
Dosage: 10 mg amoxicillin and 2.5 mg clavulanic acid/kg body weight every 12 hours equivalent to 0.25 ml reconstituted product/kg body weight every 12 hours or 5 drops per kg body weight 12 hours.
In refractory respiratory tract infections, the dose can be doubled to 20 mg amoxicillin and 5 mg clavulanic acid/kg body weight every 12 hours and the treatment can be prolonged for up to 10 days.

Dosing instructions:

Body weight (kg)	**Quantity (ml) of reconstituted veterinary medicinal product every 12 hours per dose level**	
	10 mg amoxicillin and 2.5 mg clavulanic acid/kg	**20 mg amoxicillin and 5 mg clavulanic acid/kg**
0.5 – 1	0.15 (3 drops*) to 0.25 (5 drops)	0.30 (6 drops) to 0.5 (10 drops)
>1 – 2	0.3 (6 drops) to 0.5 (10 drops)	0.6 (12 drops) to 1 (20 drops)
>2 – 3	0.55 (11 drops) to 0.75 (15 drops)	1.1 (22 drops) to 1.5 (30 drops)
>3 – 4	0.8 (16 drops) to 1 (20 drops)	1.6 (32 drops) to 2 (40 drops)

*1 drop delivers approximately 0.05 ml of the suspension.

Duration of treatment:
In most of the cases, a treatment duration of 5 to 7 days is sufficient.

For chronic cases, a longer course of therapy may be required.
Based on clinical trials, the following treatment durations are recommended:
Chronic skin infections, 10–20 days.
Chronic cystitis, 10–28 days.

9. Advice on correct administration

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

Open the bottle. Discard the original aluminium cap. Reconstitute the powder with 15 ml of tap water. Close the bottle with the dropper cap and shake vigorously to obtain a milky suspension. Open the bottle and use the dropper (graduated from 0.25 to 1 ml) to extract the prescribed amount. If needed, gently squeeze the rubber portion of the dropper to drop the excess of the veterinary medicinal product back into the bottle.
Administer the veterinary medicinal product with the graduated dropper either directly into the animal's mouth or mixed with some food.

Shake the veterinary medicinal product well before each use.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25°C.
Store the reconstituted veterinary medicinal product in a refrigerator (2°C - 8°C).
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.
Shelf life after reconstitution according to directions: 7 days.

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

Cardboard box containing 1 x 15 ml bottle and 1 x graduated dropper.

15. Date on which 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 events>:

Manufacturer responsible for batch release:
Haupt Pharma Latina S.r.l.
Strada Statale 156 Dei Monti Lepini Km 47,600
Latina
04100
Italy

<Local representatives <and contact details to report suspected adverse events>:>