ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxitab 50 mg tablets for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Amoxicillin 50 mg (equivalent to 57.5 mg amoxicillin trihydrate)

Excipients:

Qualitative composition of excipients and other constituents
Magnesium stearate
Microcrystalline cellulose
Silica, colloidal anhydrous
Sodium starch glycolate
Lactose monohydrate
Yeast (dried) from Saccharomyces cerevisiae
Chicken flavour

White to off white with brown spots, round and convex flavoured tablet with a cross-shaped break line on one side.
Tablets can be divided into equal halves and quarters.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats

3.2 Indications for use for each target species

Treatment of primary and secondary infections of the airways, such as rhinitis caused by *Pasteurella* spp. and *Streptococcus* spp., and bronchopneumonia caused by *Pasteurella* spp., *Escherichia coli* and Gram-positive cocci.
Treatment of primary infections of the urogenital tract, such as pyelonephritis and infections of the lower urinary tract caused by *Escherichia coli, Proteus* spp. and Gram-positive cocci, endometritis caused by *Escherichia coli, Streptococcus canis* and *Proteus* spp., and vaginitis as a result of mixed infections.
Treatment of mastitis caused by Gram-positive cocci and *Escherichia coli*.
Treatment of local skin infections caused by *Streptococcus* spp..

3.3 Contraindications

Do not use in case of hypersensitivity to penicillins or other substances of the β-lactam group or to any of the excipients.
Do not use in gerbils, guinea pigs, hamsters, rabbits and chinchillas.

Do not use in animals with serious renal dysfunction accompanied by anuria or oliguria.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In animals with hepatic and renal dysfunction, the dosing regimen should be carefully evaluated and the use of the veterinary medicinal product based on a risk/benefit evaluation by the veterinary surgeon.
Caution is advised in the use in small herbivores other than those in the section 3.3
The use of the veterinary medicinal product should be based on identification and susceptibility testing of the pathogens. If this is not possible, treatment should be based on epidemiological data and knowledge of the susceptibility of the target bacteria at farm or local / regional level. When using the veterinary medicinal product, the official national and regional regulations on the use of antibiotics must be observed.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin and may decrease the effectiveness of treatment with other beta lactam antimicrobials or other classes of antimicrobials due to the potential for cross resistance.

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.
Handle this product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
Wash hands after handling the tablets.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Uncommon (1 to 10 animals / 1,000 animals treated):	Hypersensitivity reactions (allergic skin reactions, anaphylaxis)[1]
Undetermined frequency (cannot be estimated from the available data)	Digestive tract disorders (diarrhoea and vomiting)[2]

[1] In these cases, administration should be discontinued and a symptomatic treatment given.
[2] Mild

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

Pregnancy and lactation:

Laboratory studies in animals have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. As no studies have been carried out in pregnant or lactating dogs and cats, use only according to the benefit/risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Chloramphenicol, macrolides, sulfonamides and tetracyclines may inhibit the antibacterial effect of penicillins because of the rapid onset of bacteriostatic action. The potential for allergic cross-reactivity with other penicillins should be considered.
Penicillins may increase the effect of aminoglycosides.

3.9 Administration routes and dosage

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

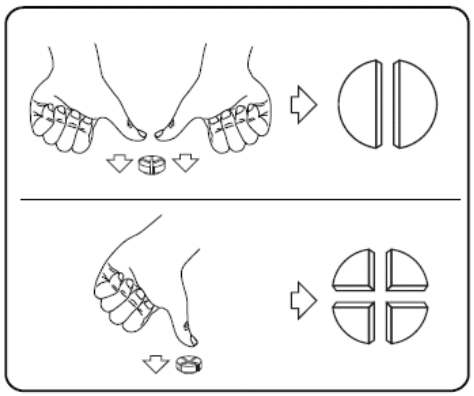
Dosage
The recommended dose is 10 mg amoxicillin per kg bodyweight, twice daily for a minimum of 5 consecutive days. The majority of routine cases respond after between 5 and 7 days of therapy. If no improvement is observed after 5 – 7 days, the diagnosis should be reassessed. In chronic or refractory cases, a longer course of therapy may be required.
The following table is intended as a guide to dispensing the veterinary medicinal product at the standard dose rate of 10 mg per kg bodyweight twice daily.

	Number of tablets twice daily		
Body weight (kg)	veterinary medicinal product **50 mg for dogs and cats**	veterinary medicinal product **250 mg for dogs**	veterinary medicinal product **500 mg for dogs**
1 – 1.25	¼		
>1.25 – 2.5	½		
>2.5 – 3.75	¾		
>3.75 – 5	1		
>5 – 6.25	1 ¼	or ¼	
>6.25 – 12.5		½	or ¼
>12.5 – 18.75		¾	
>18.75 - 25		1	or ½
>25 – 31.25		1 ¼	
>31.25 – 37.5		1 ½	or ¾
>37.5 - 50		2	or 1

>50 – 62.5			
>62.5 - 75			

 = ¼ Tablet  = ½ Tablet  = ¾ Tablet  = 1 Tablet

Tablets can be divided into equal halves or quarters to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



Equal halves: press down with your thumbs on both sides of the tablet.
Equal quarters: press down with your thumb in the middle of the tablet.

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

In case of overdose no other adverse events are known than those described in section 3.6.

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

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01CA04

4.2 Pharmacodynamics

General Properties
Amoxicillin is a beta-lactam antibiotic and its structure contains the beta-lactam ring and thiazolidine ring common to all penicillins. Beta-lactam antibiotics prevent the bacterial cell wall from forming 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 but cause lysis of growing cells only. Beta-lactam antibiotics can be referred to as a time-dependent antibiotic.

Antimicrobial spectrum

Amoxicillin is a broad spectrum antibiotic and generally active against some Gram-negative and most Gram-positive bacteria (Germ-vet 2007) e.g. penicillin sensitive *Pasteurella* spp., *Proteu*s spp, *Streptococcus* spp., *E. coli* and Gram-positive cocci.

Resistance
Amoxicillin is acid-resistant but is not resistant to the action of beta-lactamases, which can hydrolyse the molecules causing the beta-lactam ring structure to open, causing inactivity of the antibiotic.
Most Gram-negative bacteria are intrinsically resistant to many beta-lactam drugs. This is partly due to the mechanism of action of the drug and the structure of the membrane of the bacteria.
Acquired resistance to beta-lactam drugs in clinical isolates may be due to beta-lactamase activity specified by plasmids or to mutational changes in chromosomal loci. In some strains a single step mutation may be responsible for resistance, whereas in others resistance may be due to several mutations.
Acquired resistance prevalence may be high in *E. coli*.

4.3 Pharmacokinetics

Amoxicillin is well absorbed after oral administration. In dogs, the systemic bioavailability is 60-70 %. Amoxicillin has a relatively small apparent distribution volume, low plasma-protein binding (34 % in dogs) and a short elimination half-life period due to active tubular excretion by the kidneys.
After absorption, highest concentrations are found in the kidneys (urine) and bile, followed by the liver, lungs, heart and spleen.
Distribution of amoxicillin into cerebrospinal fluid is low unless the meninges are inflamed.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: return any unused tablet portion to the open blister and use within 4 days.

5.3 Special precautions for storage

Do not store above 30 ° C.

5.4 Nature and composition of immediate packaging

Aluminium - PVC/PE/PVDC blister
Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 25 or 50 blisters of 10 tablets
Cardboard box containing 10 separate cardboard boxes, each containing 1 blister of 10 tablets
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

CP-Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

402365.00.00

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 12/12/2016

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

MM/YYYY

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*).

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxitab 50 mg tablets for dogs and cats

2. STATEMENT OF ACTIVE SUBSTANCES

Amoxicillin 50 mg (equivalent to 57.5 mg amoxicillin trihydrate) / tablet

3. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
40 tablets
50 tablets
60 tablets
70 tablets
80 tablets
90 tablets
100 tablets
250 tablets
500 tablets

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, return any unused tablet portion to the open blister and use within 4 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.

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

Read the package leaflet before use.

User warnings: Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

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

CP-Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

402365.00.00

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Alu/PVC/PE/PvDC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxitab 50 mg tablets for dogs and cats

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Amoxicillin 50 mg (equivalent to 57.5 mg amoxicillin trihydrate) / tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, return any unused tablet portion to the open blister and use within 4 days.

5. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Amoxitab 50 mg tablets for dogs and cats

2. Composition

Each tablet contains:

Active substance:

Amoxicillin 50 mg (equivalent to 57.5 mg amoxicillin trihydrate)

White to off white with brown spots, round and convex flavoured tablet with a cross-shaped break line on one side. Tablets can be divided into equal halves and quarters.

3. Target species

Dogs and cats

4. Indications for use

Treatment of primary and secondary infections of the airways, such as rhinitis caused by *Pasteurella* spp. and *Streptococcus* spp. and bronchopneumonia caused by *Pasteurella* spp., *Escherichia coli* and Gram-positive cocci.
Treatment of primary infections of the urogenital tract, such as pyelonephritis and infections of the lower urinary tract caused by *Escherichia coli, Proteus* spp. and Gram-positive cocci, endometritis caused by *Escherichia coli, Streptococcus canis* and *Proteus* spp. and vaginitis as a result of mixed infections.
Treatment of mastitis (inflammation of the mammary gland) caused by Gram-positive cocci and *Escherichia coli*.
Treatment of local skin infections caused by *Streptococcus* spp..

5. Contraindications

Do not use in case of hypersensitivity to penicillins or other substances of the β-lactam group (i.e. cephalosporins) or to any of the excipients.
Do not use in gerbils, guinea pigs, hamsters, rabbits and chinchillas.
Do not use in animals with serious renal dysfunction accompanied by anuria or oliguria (no or very low output of urine).

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:

In animals with hepatic and renal dysfunction, the dosing regimen should be carefully evaluated and the use of the veterinary medicinal product based on a risk/benefit evaluation by the veterinary surgeon.
Caution is advised in the use in small herbivores other than those in the section '*Contraindications*'.
The use of the veterinary medicinal product should be based on identification and susceptibility testing of the pathogens. If this is not possible, treatment should be based on epidemiological data and knowledge of the susceptibility of the target bacteria at farm or local / regional level. When using the veterinary medicinal product, the official national and regional regulations on the use of antibiotics must be observed
Use of the veterinary medicinal product deviating from the instructions given in this leaflet may increase the prevalence of bacteria resistant to amoxicillin and may decrease the effectiveness of treatment with other beta-lactam antimicrobials or other classes of antimicrobials due to the potential for cross resistance.

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.
Handle this product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
Wash hands after handling the tablets.

Pregnancy and lactation:

Laboratory studies in animals have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. As no studies have been carried out in pregnant or lactating dogs and cats, use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Chloramphenicol, macrolides, sulfonamides and tetracyclines may inhibit the antibacterial effect of penicillins because of the rapid onset of bacteriostatic action. The potential for allergic cross-reactivity with other penicillins should be considered.
Penicillins may increase the effect of aminoglycosides.

Overdose:

In case of overdose no other adverse events are known than those described in section '*Adverse events*'.

7. Adverse events

Dogs and cats:

Uncommon (1 to 10 animals / 1,000 animals treated):	Hypersensitivity reactions (allergic skin reactions, anaphylaxis)[1]

Undetermined frequency (cannot be estimated from the available data)	Digestive tract disorders (diarrhoea and vomiting)[2]

[1] In these cases, administration should be discontinued and a symptomatic treatment given.
[2] Mild

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:

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

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

Dosage
The recommended dose is 10 mg amoxicillin per kg bodyweight, twice daily for a minimum of 5 consecutive days. The majority of routine cases respond after between 5 and 7 days of therapy. If no improvement is observed after 5 – 7 days, the diagnosis should be re-assessed. In chronic or refractory cases, a longer course of therapy may be required.

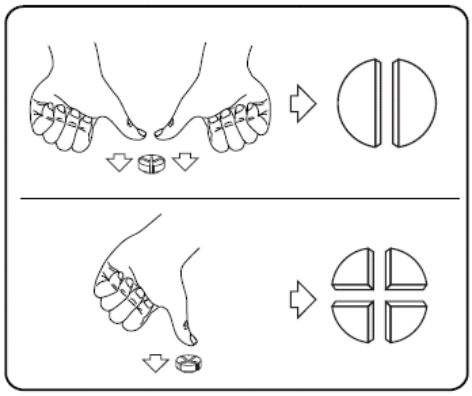
The following table is intended as a guide to dispensing the veterinary medicinal product at the standard dose rate of 10 mg per kg bodyweight twice daily.

	Number of tablets twice daily		
Body weight (kg)	veterinary medicinal product **50 mg for dogs and cats**	veterinary medicinal product **250 mg for dogs**	veterinary medicinal product **500 mg for dogs**
1 – 1.25			
>1.25 – 2.5			
>2.5 – 3.75			
>3.75 – 5			
>5 – 6.25		or 	
>6.25 – 12.5			or 
>12.5 – 18.75			
>18.75 - 25			or 
>25 – 31.25			
>31.25 – 37.5			or 
>37.5 - 50			or 
>50 – 62.5			
>62.5 - 75			

 = ¼ Tablet  = ½ Tablet  = ¾ Tablet  = 1 Tablet

9. Advice on correct administration

Tablets can be divided into equal halves or quarters to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



Equal halves: press down with your thumbs on both sides of the tablet.
Equal quarters: press down with your thumb in the middle of the tablet.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: return any unused tablet portion to the open blister and use within 4 days.

12. Special precautions for disposal

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

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

402365.00.00

Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 25 or 50 blisters of 10 tablets
Cardboard box containing 10 separate cardboard boxes, each containing 1 blister of 10 tablets.
Not all pack sizes may be marketed.

Divisible tablet

15. Date on which the package leaflet was last revised

MM/YYYY

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany
Tel.: **Please include this information*
E-Mail: **Please include this information*

Manufacturer responsible for batch release:

Lelypharma B.V.
Zuiveringweg 42
4283 PZ Lelystad
The Netherlands

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

Local representatives and contact details to report suspected adverse reactions: