ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxival vet 200 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains :
Active substance :

Amoxicillin.....200.00 mg
(As Amoxicillin trihydrate ..... 229.60 mg)

Excipients:

Qualitative composition of excipients and other constituents
Biscuit flavour containing Sodium benzoate (E 211)
Deactivated Yeast (Saccharomyces cerevisae)
Ammonium glycyrrhizate
Magnesium stearate
Anhydrous colloidal silica
Croscarmellose sodium
Cellulose, microcrystalline

Round, beige cross-scored tablets that can be divided in half.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

Treatment of bacterial infections of the alimentary, respiratory and urogenital tracts and skin and wound infections caused by susceptible organisms.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to penicillins, to other antimicrobials of the β-lactam group or to any of the excipients.
Do not use in animals with serious dysfunction of the kidneys accompanied by anuria or oliguria
Do not use in rabbits, guinea pigs, hamsters, gerbils and chinchillas.
Do not use in the presence of β-lactamase producing bacteria.
Do not use where resistance against β-lactam antibiotics exists.

3.4 Special warnings

None known

3.5 Special precautions for use

Special precautions for safe use in the target species:

Official, national and regional antimicrobial policies with respect to the use of broad-spectrum antibiotics should be taken into account.
It is advised that upon initiating therapy appropriate sensitivity testing is performed.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the amoxicillin, and may decrease the effectiveness of treatment with beta-lactam antibiotics
Caution is advised in the use in small herbivores other than those in the section 3.3.

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 reaction to these substances may occasionally be serious.
Do not handle this veterinary medicinal product if you know you are sensitized, 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.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Undetermined frequency (cannot be estimated from the available data):	Diarrhoea, Vomiting Allergic reaction[1]

[1] In case of allergic reaction, stop treatment.

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 laying

Pregnancy and lactation:

The veterinary medicinal product should be used during pregnancy or lactation only according to the risk-benefit analysis performed by the veterinarian.
Laboratory studies (rat, mice) did not show embryotoxicity or teratogenicity except at high doses.

3.8 Interaction with other medicinal products and other forms of interaction

The bactericidal effect of amoxicillin is neutralized by simultaneous use of bacteriostatic acting antimicrobials (macrolides, sulfonamides and tetracyclines).
Penicillins may increase the effect of aminoglycosides.

3.9 Administration routes and dosage

Oral use.
10 mg of amoxicillin/kg body weight twice daily for 5 consecutive days or longer depending on clinical response.

Tablets can be divided in half:

Bodyweight (kg)	Number of tablets twice daily
>5 -10<	0.5
>10 -20<	1
>20-30<	1,5
>30 -40<	2

The tablets are flavoured and can be given directly in the mouth or added to food if necessary. To achieve optimum bioavailability of amoxicillin, the first mode of administration should be preferred and the tablets administered apart from meals.

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

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

The toxicity of amoxicillin in domestic carnivores is very low. A part from occasional instances of diarrhoea, which have been reported with the recommended dose, no adverse side effects are to be expected from accidental overdose. In case of overdose, further symptoms like central nervous excitation manifestation or cramps could appear.

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

4.1ATCvet code: QJ01CA04

4.2 Pharmacodynamics

Amoxicillin has a bactericidal activity; it causes deterioration of the bacterial cell walls, rendering the bacteria fragile, resulting in death during division. The activity results from the induction of an alteration of membrane peptidoglycans. Amoxicillin is effective against most Gram+ bacteria (except for *Staphylococcus* strains producing β-lactamases) and towards a large number of Gram- bacteria. It is active against most anaerobes (except for *Bacteroides fragilis* producing β-lactamases). Bacteria usually sensitive belong to the species *Streptococcus* spp, *Staphylococcus* spp., *Haemophilus* spp., *Proteus* spp., *Pasteurella* spp and *Clostridium* spp.Amoxicillin is less effective against E. coli bacteria which tends to be resistant. The bactericidal activity of amoxicillin *in vitro* is well correlated with its therapeutic properties *in vivo*.

4.3 Pharmacokinetics

In dogs, the systemic availability of amoxicillin is about 60 to 70 %. Amoxicillin has a low volume of distribution, a low degree of protein binding (approximately 13 %) and a short elimination half–life of approximately 1-2 hours requiring frequent administrations.
After absorption, the highest concentrations of amoxicillin are reached in kidneys (urine) and bile, then in liver, lungs, heart and spleen. Distribution of amoxicillin into cerebrospinal fluids is low unless the meninges are inflamed.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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: 12 hours.

5.3 Special precautions for storage

Do not store above 25 °C.
Any part-used tablet should be returned to the opened blister and used within 12 hours.

5.4 Nature and composition of immediate packaging

PVC/Aluminium heat-sealed blister.

Cardboard box of 1 blister x 10 tablets (10 tablets)
Cardboard box of 2 blisters x 10 tablets (20 tablets)
Cardboard box of 20 blisters x 10 tablets (200 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 AUTORISATION HOLDER

7. MARKETING AUTHORISATION NUMBERS

8. DATE OF FIRST AUTHORISATION:

Date of first authorisation: {DD/MM/YYYY}

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxival vet 200 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains:
200 mg of Amoxicillin

3. PACKAGE SIZE

10 tablets
20 tablets
200 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.{mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Any part-used tablet should be returned to the opened blister and used within 12 hours.

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
Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxival vet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

200 mg of Amoxicillin.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Amoxival vet 200 mg tablets for dogs

2. Composition

One tablet contains:
Active substance:
Amoxicillin..... 200 mg
(As Amoxicillin trihydrate ..... 229.60 mg)

Round, beige cross-scored tablets that can be divided in half.

3. Target species

Dogs

4. Indications for use

Treatment of bacterial infections of the alimentary, respiratory and urogenital tracts and skin and wound infections caused by susceptible organisms

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, to penicillins or other substances of the β-lactamines group or to any excipients
Do not use in animals with serious dysfunction of the kidneys accompanied by anuria or oliguria.
Do not use in rabbits, guinea pigs, hamsters, gerbils and chinchillas.
Do not use in the presence of β-lactamase producing bacteria.
Do not use where resistance against β-lactam antibiotics exists.

6. Special warnings

Special precautions for safe use in the target species:
Official, national and regional antimicrobial policies with respect to the use of broad-spectrum antibiotics should be taken into account.
Do not use in case of bacteria sensitive to narrow spectrum penicillins or to amoxicillin as single substance.
It is advised that upon initiating therapy appropriate sensitivity testing is performed.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the amoxicillin, and may decrease the effectiveness of treatment with beta-lactam antibiotics
Caution is advised in the use in small herbivores other than those in the section Contra-indications

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 reaction to these substances may occasionally be serious.

Do not handle this veterinary medicinal product if you know you are sensitized, 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.
Wash hands after use.

Use during pregancy, lactation or laying:
The veterinary medicinal product should be used during pregnancy or lactation only according to the risk-benefit analysis performed by the veterinarian.
Laboratory studies (rat, mice) did not show embryotoxicity or teratogenicity except at high doses.

Interaction with other medicinal products and other forms of interaction:
The bactericidal effect of amoxicillin is neutralized by simultaneous use of bacteriostatic acting antimicrobials (macrolides, sulfonamides and tetracyclines).
Penicillins may increase the effect of aminoglycosides

Overdose:
The toxicity of amoxicillin in domestic carnivores is very low. A part from occasional instances of diarrhoea, which have been reported with the recommended dose, no adverse side effects are to be expected from accidental overdose. In case of overdose, further symptoms like central nervous excitation manifestation or cramps could appear.

7. Adverse events

Dogs:

Undetermined frequency (cannot be estimated from the available data):
Diarrhoea, Vomiting Allergic reaction[1]

[1] In case of allergic reaction, stop treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

Oral use.
10 mg of amoxicillin/kg body weight twice daily for 5 consecutive days or longer depending on clinical response.

Tablets can be divided in half:

Bodyweight (kg)	Number of tablets twice daily
>5 -10<	0.5
>10 -20<	1
>20-30<	1,5

>30 -40<	2

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

9. Advice on correct administration

The tablets are flavoured and can be given directly in the mouth or added to food if necessary. To achieve optimum bioavailability of amoxicillin, the first mode of administration should be preferred and the tablets administered apart from meals.

10. Withdrawal periods

Not applicable

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Any part-used tablet should be returned to the opened blister and used within 12 hours
Do not use the veterinary medicinal product after the expiry date which are stated on the blister and the outer carton after Exp. The expiry date refers to the last day of that month.

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 authorization numbers and pack sizes

(MA)

Pack sizes:
Cardboard box of 1 blister x 10 tablets (10 tablets)
Cardboard box of 2 blisters x 10 tablets (20 tablets)
Cardboard box of 20 blisters x 10 tablets (200 tablets)

Not all pack sizes may be marketed.

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 contact details to report suspected adverse reactions:
(Name and address to be completed nationally)
Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

Manufacturer for the batch release:

Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 LOUVERNE
FRANCE