Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 250 mg palatable tablets for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
Amoxicillin (as amoxicillin trihydrate) 200 mg
Clavulanic acid (as potassium salt) 50 mg

Excipients
Brown iron oxide (E172) 0.475 mg
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
Beige scored tablet that can be divided into two equal parts.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

In dogs: treatment or adjunctive treatment of periodontal infections caused by bacteria susceptible to amoxicillin in combination with clavulanic acid i.e. *Pasteurella* spp, *Streptococcus* spp and *Escherichia coli*.

4.3 Contraindications

Do not use in cases of hypersensitivity to penicillins or other substances of the β-lactam group or to any of the excipients.
Do not administer to gerbils, guinea pigs, hamsters, rabbits and chinchillas.
Do not administer to horses and ruminating animals.
Do not use in animals with serious dysfunction of the kidneys accompanied by anuria or oliguria.
Do not use in cases of known resistance to the combination of amoxicillin and clavulanic acid.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

In animals with impaired liver and kidney function, the use of the product should be subject to a risk/benefit evaluation by the veterinary surgeon and the posology evaluated carefully.
Caution is advised in the use in small herbivores other than those in 4.3.
Use of the product should be based on susceptibility testing.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin/clavulanic acid and may decrease the effectiveness of treatment with other β-lactam antibiotics, due to the

potential for cross resistance. Use of the product should take into account official and local antimicrobial policies. Do not use in cases of bacteria sensitive to narrow spectrum penicillins or to amoxicillin as a single substance.

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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. 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.

4.6 Adverse reactions (frequency and seriousness)

Vomiting and diarrhoea may be observed very rarely. Treatment may be discontinued depending on the severity of the undesirable effects and a benefit/risk evaluation by the veterinary surgeon.
Hypersensitivity reactions (allergic skin reactions, anaphylaxis) may be observed very rarely. In these cases, administration should be discontinued and a symptomatic treatment given.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the product has not been established during pregnancy and lactation. Laboratory studies in rats have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Use only in accordance with the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

The bactericidal activity of amoxicillin may be reduced by the simultaneous use of bacteriostatic substances such as macrolides, tetracyclines, sulfonamides and chloramphenicol.
The potential for allergic cross-reactivity with other penicillins should be considered.
Penicillins may increase the effect of aminoglycosides.

4.9 Amounts to be administered and administration route

For oral administration
To ensure the correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.

The recommended dose of the product is 10 mg amoxicillin /2.5 mg clavulanic acid per kg body weight twice a day by the oral route in dogs, i.e. 1 tablet per 20 kg body weight every 12 h, according to the following table:

Bodyweight (kg)	Number of tablets twice daily
[8.1 - 10]	½
[10.1- 20]	1
[20.1- 30]	1 ½
[30.1- 40]	2

For dogs, in severe periodontal infections the dose may be doubled to 20 mg amoxicillin / 5 mg clavulanic acid/kg body weight twice daily.

Duration of treatment:
- 7 days for the treatment of periodontal infections in dogs.

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

At three times the recommended dose for a period of 28 days, diarrhoea was observed in dogs. In the event of an overdose symptomatic treatment is advised.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: anti-infective for systemic use; amoxicillin and enzyme inhibitor.
ATCvet code: QJ01CR02

5.1 Pharmacodynamic properties

Amoxicillin is an aminobenzylpenicillin from the β-lactam penicillin family which prevents the bacterial cell wall formation by interfering with the final step of peptidoglycan synthesis.

Clavulanic acid is an irreversible inhibitor of intracellular and extracellular β-lactamases which protects amoxicillin from inactivation by many β-lactamases.

Amoxicillin/clavulanate has a wide range of activity which includes β-lactamase producing strains of both Gram-positive and Gram-negative aerobes, facultative anaerobes and obligate anaerobes.

In absence of specific veterinary breakpoints, the following human derived breakpoints (M100-S document) could be used for any other animal species/bacterial species/infection type combination:Amoxicillin/clavulanic acid breakpoints (NCCLS/2002):
Staphylococci: sensitive: MIC < 4/2 µg/ml, resistant: MIC > 8/4 µg/ml
Other organisms: sensitive: MIC < 8/4 µg/ml, resistant: MIC > 32/16 µg/ml

In dog periodontal infections in Europe (isolates of the year 2002 from France, Germany and Belgium) amoxicillin/clavulanic acid combination in a ratio 2/1 showed the following data on sensitivity:

Pasteurellaceae: MIC_{90}: 0.4/0.2 µg/ml,
Streptococcus spp.: MIC_{90}: 0.4/0.2 µg/ml,
Escherichia coli: MIC_{90}: 5.3/2.6 µg/ml,

Resistance to β-lactam antibiotics is mainly mediated by β-lactamases which hydrolyze antibiotics such as amoxicillin.

Susceptibility and resistance patterns can vary with geographical area and bacterial strain, and may change over time.

5.2 Pharmacokinetic particulars

After oral administration at the recommended dose in dogs, the absorption of amoxicillin and clavulanic acid is fast. The maximum plasma concentration of amoxicillin of 8.5 µg/ml is reached in 1.4 hours and the maximum plasma concentration of clavulanic acid of 0.9 µg/ml is reached in 0.9hours. Half life is 1 hour for both substances.
Elimination is also fast. 12 % of the amoxicillin and 17 % of clavulanic acid is excreted in the urine. The remainder is excreted as inactive metabolites.
After repeated oral administration of the recommended dose, there is no accumulation of amoxicillin or clavulanic acid and the steady state is reached rapidly after first administration.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brown iron oxide E172
Crospovidone
Povidone K25
Silicon dioxide
Microcrystalline cellulose
Liver aroma
Yeast aroma
Magnesium stearate
Hypromellose

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 16 hours

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.
Return any halved tablet to the opened blister-pack and use within 16 hours.

6.5 Nature and composition of immediate packaging

Aluminium/aluminium blister pack with 10 tablets/blister
Cardboard box: Pack sizes of 10, 20, 50, 100, 120, 150, 200, 250, 300, 400, 500, 600, 750 and 1000 tablets
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/048/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st October 2005
Date of last renewal: 20th August 2010

10 DATE OF REVISION OF THE TEXT

December 2019