

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 250 mg Palatable tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:

Active ingredients:

Amoxicillin (as amoxicillin trihydrate).....200 mg
Clavulanic acid (as potassium salt).....50 mg

Excipients

Brown iron oxide (E172).....0.475 mg

3 PHARMACEUTICAL FORM

Tablet

Beige scored tablet

4 PHARMACOLOGICAL PROPERTIES

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

ATC Vet code: QJ01CR02

4.1 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 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:

Streptococcus spp.: MIC₉₀: 0.4/0.2 μ g/ml,
Pasteurellaceae: MIC₉₀: 0.4/0.2 μ g/ml,
Escherichia coli: MIC₉₀: 5.3/2.6 μ g/ml,
Enterobacteriaceae: MIC₉₀: 22.6/11.3 μ g/ml, except for *Enterobacter* spp.

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Pseudomonadaceae: MIC₉₀: 147.0/73.5 µg/ml,

Enterobacter spp.: MIC₉₀: 49.6/24.8 µg/ml

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

Resistance to β-lactam antibiotics is mainly mediated by β-lactamases which hydrolyze antibiotics such as amoxicillin. It is mostly shown in *Pseudomonadaceae* (81.25%) and in *Enterobacter* spp. (55.5%).

4.2 PHARMACOKINETIC PROPERTIES

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 h and the maximum plasma concentration of clavulanic acid of 0.9 µg/ml is reached in 0.9h.

Elimination is also fast.

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.

5 CLINICAL PARTICULARS

5.1 TARGET SPECIES

Dogs

5.2 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*.

5.3 CONTRA-INDICATIONS

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

Do not administer to gerbils, guinea pigs, hamsters, rabbits and chinchillas.

5.4 UNDESIRABLE EFFECTS (FREQUENCY AND SERIOUSNESS)

Vomiting and diarrhoea may be observed. 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. In these cases, administration should be discontinued and a symptomatic treatment given.

5.5 SPECIAL PRECAUTIONS FOR USE

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.

In addition to section 5.3 contra-indications, use with care in other small pet (non-food producing) herbivores.

Use of the product should be based on susceptibility testing.

5.6 USE DURING PREGNANCY AND LACTATION

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 the product only accordingly to the benefit/risk assessment by the responsible veterinarian.

5.7 INTERACTION WITH OTHER VETERINARY MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

The bactericidal activity of amoxicillin may be reduced by the simultaneous use of bacteriostatic substances such as macrolides, tetracyclines, sulfonamides and chloramphenicol.

5.8 POSOLOGY AND ADMINISTRATION

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

Duration of treatment: 7 days.

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

5.9 OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES)

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.

5.10 SPECIAL WARNINGS FOR EACH TARGET SPECIES

None known.

5.11 WITHDRAWAL PERIOD

Not applicable.

5.12 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

6 PHARMACEUTICAL PARTICULARS

6.1 MAJOR INCOMPATIBILITIES

None known

6.2 SHELF-LIFE

2 years.

6.3 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.4 NATURE AND CONTENTS OF CONTAINER

Aluminium/aluminium strip pack with 10 tablets/strip

Cardboard box with 1 strip
Cardboard box with 5 strips
Cardboard box with 12 strips
Cardboard box with 20 strips
Cardboard box with 30 strips
Cardboard box with 50 strips
Cardboard box with 75 strips

Cardboard box with 2 strips
Cardboard box with 10 strips
Cardboard box with 15 strips
Cardboard box with 25 strips
Cardboard box with 40 strips
Cardboard box with 60 strips
Cardboard box with 100 strips

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6.5 SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED MEDICINAL PRODUCT OR WASTE MATERIALS, IF ANY

Any unused product or waste material should be disposed of in accordance with the national requirements.

7 NAME OR CORPORATE NAME AND ADDRESS OR REGISTERED PLACE OF BUSINESS OF THE MARKETING AUTHORISATION HOLDER

Vétoquinol UK Limited
Vétoquinol House
Great Slade
Buckingham Industrial Park
Buckingham MK18 1PA
UK

Marketing authorisation number: Vm 08007/4114

Date of first authorisation : 18 June 2004

Date of revision of SPC : 1 June 2005

Conditions of supply :

POM