SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 50 mg Palatable tablets for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Amoxicillin (as amoxicillin trihydrate)……..……40 mg
Clavulanic acid (as potassium salt)……..10 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Brown iron oxide (E172)	0.095mg
Crospovidone	
Povidone K25	
Silicon dioxide	
Microcrystalline cellulose	
Liver aroma	
Yeast aroma	
Magnesium stearate	
Hypromellose	

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each 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*.

In cats: treatment of skin infections (including wounds and abscesses) caused by bacteria susceptible to amoxicillin in combination with clavulanic acid i.e. *Pasteurella* spp, *Staphylococcus* spp, *Streptococcus* spp and *Escherichia coli.*

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 3.3.
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 veterinary medicinal product if you know you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this veterinary medicinal 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 package leaflet or the label to the physician. 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:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1], diarrhoea[1] Hypersensitivity reaction[2] (allergic skin reaction[2]), anaphylaxis[2]

[1] Treatment may be discontinued depending on the severity of the undesirable effects and a benefit/risk evaluation by the veterinary surgeon.
[2] In these cases, administration should be discontinued and a symptomatic treatment given

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 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:

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.

3.8 Interaction with other 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. 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

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 and cats, i.e. 1 tablet per 4 kg body weight every 12 h, according to the following table:

Bodyweight (kg)	Number of tablets twice daily
[1.0 - 2.0]	½
[2.1 - 4.0]	1
[4.1 - 6.0]	1 ½
[6.1 - 8.0]	2

In severe infections in each target species, 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.
- 7 days for the treatment of skin infections in cats (including wounds and abscesses).

The clinical status of animals should be re-evaluated after 7 days and the treatment prolonged for a further 7 days if necessary. Severe cases of skin infection may require an even longer duration of treatment and this should be at the discretion of the responsible veterinarian.

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

At three times the recommended dose for a period of 28 days, a decrease in cholesterol values and episodes of vomiting were observed in cats and diarrhoea was observed in dogs. In the event of an overdose symptomatic treatment is advised.

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: QJ01CR02

4.2 Pharmacodynamics

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.

According to CLSI document VET01-S2, amoxicillin/clavulanic acid breakpoints are for feline skin and soft tissue infections and for the following organisms (*Staphylococcus* spp., *Streptococcus* spp., *Escherichia coli* and *Pasteurella multocida*): sensitive: MIC 1/0.5 µg/ml.

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:
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,

In cat and dog dermatological infections in Europe (isolates between the year 2010 and 2013 from The Netherlands, France, Germany, The United Kingdom and Belgium) amoxicillin/clavulanic acid combination in a ratio 2/1 showed the following data on sensitivity:

Data for the period 2010-2013	n	Range of MIC (µg/mL)	MIC_{50} (µg/mL)	MIC_{90} (µg/mL)
Pasteurella multocida	4-17	0.06/0.03 - 0.5/0.25	0.166/0.083[2]	0.232/0.116[2]
Staphylococcus spp	29-33	0.06/0.03 - 32/16	0.102/0.051 - 0.170/0.085 -	0.835/0.418 - 11.578/5.789
Streptococcus	11-12	0.015/0.0080.	0.013/0.006 -	0.023/0.012 -

spp[1]		03/0.015	0.027/0.014	0.027/0.014
Escherichia coli	1-4	1/0.5 - 64/32	ND	ND

[1] MIC values determined in 2012 and 2013;
[2] MIC_{50} and MIC_{90} could be determined in 2013 only;
ND: Not Determined due to low sample size

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.

4.3 Pharmacokinetics

After oral administration at the recommended dose in dogs and cats, the absorption of amoxicillin and clavulanic acid is fast. In dogs, 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 0.9 hours. Half-life is 1 hour in dogs for both substances.
In cats, the maximum plasma concentration of amoxicillin of 6.6 µg/ml is reached in 1.8 hours and the maximum plasma concentration of clavulanic acid of 3.7 µg/ml is reached in 0.75 hours. Half-life is 1 to 2 hours in cats 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 in dogs and cats, there is no accumulation of amoxicillin or clavulanic acid and the steady state is reached rapidly after first administration.

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: 16 hours.

5.3 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.

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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

Vetoquinol UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 08007/5007

8. DATE OF FIRST AUTHORISATION

18 June 2004

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

May 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Approved 27 May 2026
Gavin Hall