VETOQUINOL	**Nom du produit :** CLAVASEPTIN 250 ml MY	
Créé par : P.JARDEL	**Référence article :**	**0918 D L**
le :	**Dimensions :** 240x210	
Visa :	**1 couleur**	

281 U

vetoquinol

CLAVASEPTIN® 250 mg *Tablets for dogs*

Name and address of manufacturer
VETOQUINOL
Magny-Vernois
70200 Lure
France

Name and address of the Marketing authorization holder
GLADRON CHEMICALS SDN. BHD.
No. 7, Jalan TP 7,
UEP Industrial Park, 40400 Shah Alam,
Selangor Darul Ehsan,
Malaysia

COMPOSITION
Each 476 mg scored tablet contains:
Amoxicillin (as amoxicillin trihydrate) . . . . . 200 mg
Clavulanic acid (as potassium clavulanate) . . . 50 mg
Oblong, off-white to brownish sprinkled, scored tablets of about 17 mm length.

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.

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:

Streptococcus spp.:	MIC_{90}: 0.4/0.2 µg/ml,
Pasteurellaceae:	MIC_{90}: 0.4/0.2 µg/ml,
Escherichia coli:	MIC_{90}: 5.3/2.6 µg/ml,
Enterobacteriaceae:	MIC_{90}: 22.6/11.3 µg/ml, except for Enterobacter spp.
Pseudomonadaceae:	MIC_{90}: 147.0/73.5 µg/ml,
Enterobacter spp.:	MIC_{90}: 49.6/24.8 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%).

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

PHARMACOKINETICS
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. 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.

UNUSED PRODUCT OR WASTE MATERIALS, IF ANY
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

INDICATIONS
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*.

DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION
10 mg amoxicillin and 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

In severe infections, the dose may be doubled to 20 mg amoxicillin and 5 mg clavulanic acid/kg body weight twice daily.

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

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

CONTRAINDICATIONS
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. 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.

SPECIAL WARNINGS
Special precautions for use in animals
In addition to section contraindications:
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 mentioned in contrainidcations.
Use of the product should be based on susceptibility testing.
Inappropriate use of the product may increase the prevalence of bacteria resistant to amoxicillin/clavulanic acid. 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.

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

INTERACTION WITH OTHER MEDICINAL PRODUCTS
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.

OVERDOSE AND TREATMENT
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.

ADVERSE REACTIONS (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.

WITHDRAWAL PERIOD
Not applicable

SPECIAL STORAGE PRECAUTIONS
Keep out of reach of children.
Do not store above 25°C
Store in the original package.
Protect from moisture.
Return any halved tablet to the opened blister-pack and use within 16 hours.

DOSAGE FORM AND PACKAGING AVAILABLE
Cardboard box of 10 blisters of 10 tablets

DATE OF REVISION OF PACKAGE INSERT
February 2019

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