

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE  
BOX**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Clavaseptin 500 mg Palatable tablets for dogs  
Amoxicillin/Clavulanic acid

**2. STATEMENT OF ACTIVE SUBSTANCES**

Amoxicillin (as amoxicillin trihydrate).....400 mg  
Clavulanic acid (as potassium salt)..... 100 mg

**3. PHARMACEUTICAL FORM**

Tablet

**4. PACKAGE SIZE**

10, 20, 50, 100, 120, 150, 200, 250, 300, 400, 500, 600, 750, 1000 tablets

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Not applicable.

**9. SPECIAL WARNING(S), IF NECESSARY**

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

**10. EXPIRY DATE**

EXP {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C. Store in the original package.  
Shelf life after first opening the immediate packaging: 16 hours.  
Return any halved tablet to the opened blister-pack and use within 16 hours.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Vetoquinol UK Limited  
Steadings Barn  
Pury Hill Business Park  
Nr Alderton  
Towcester  
Northamptonshire  
NN12 7LS

**16. MARKETING AUTHORISATION NUMBER**

Vm 08007/3007

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**BLISTER**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Clavaseptin 500 mg tablets  
Amoxicillin 400 mg  
Clavulanic acid 100 mg



**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Vetoquinol

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### Clavaseptin 500 mg

#### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Vetoquinol UK Limited  
Steadings Barn  
Pury Hill Business Park  
Nr Alderton  
Towcester  
Northamptonshire  
NN12 7LS

Manufacturer responsible for batch release:

VETOQUINOL  
MAGNY-VERNOIS  
F-70200 LURE  
FRANCE

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 500 mg Palatable tablets for dogs

Amoxicillin/Clavulanic acid

#### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains:

|   |          |
|---|----------|
| Amoxicillin (as amoxicillin trihydrate) | 400 mg   |
| Clavulanic acid (as potassium salt)     | 100 mg   |
| Brown iron oxide (E172)                 | 0.950 mg |

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

#### 4. INDICATION(S)

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. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to penicillins or other substances of the  $\beta$ -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.

## 6. ADVERSE REACTIONS

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)

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

## 7. TARGET SPECIES

Dogs



## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral 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, according to the following table:



| Bodyweight (kg) | Clavaseptin 500 mg - Dogs<br>1 tablet per 40 kg bodyweight every 12 hours |
|-----------------|---|
| [ > 30 - 40 ]   | 1   |
| [ > 40 - 60 ]   | 1 ½   |
| [ > 60 - 80 ]   | 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.

**9. ADVICE ON CORRECT ADMINISTRATION**

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

**10. WITHDRAWAL PERIOD(S)**

Not applicable.

**11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

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

Shelf life after first opening the immediate packaging: 16 hours.

Return any halved tablet to the opened blister-pack and use within 16 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

**12. SPECIAL WARNING(S)**

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 indicated in paragraph contraindications.

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 and may decrease the effectiveness of treatment with other  $\beta$ -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

#### 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 the benefit/risk assessment by the responsible veterinarian.

#### 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.

#### 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.

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

October 2019

### **15. OTHER INFORMATION**

#### **Presentation**

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.

Revised: February 2020  
AN: 00191/2019

Approved 05 February 2020

A handwritten signature in black ink, consisting of a stylized initial followed by the name "Hunter." with a period.