ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 62.5 mg Palatable tablets for dogs and cats

Amoxicillin/Clavulanic acid

2. STATEMENT OF ACTIVE SUBSTANCES

Amoxicillin (as amoxicillin trihydrate)……..…….50 mg
Clavulanic acid (as potassium salt)……..…12.5 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

10, 100, 250, 500 tablets

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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 08007/5009

17. MANUFACTURER'S BATCH NUMBER

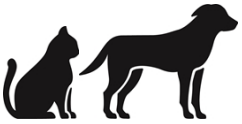
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 62.5 mg tablets



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 62.5 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 SA
MAGNY-VERNOIS
70200 LURE
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 62.5 mg Palatable tablets for dogs and cats

Amoxicillin/Clavulanic acid

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

Each tablet contains:

Amoxicillin (as amoxicillin trihydrate)	50 mg
Clavulanic acid (as potassium salt)	12.5 mg
Brown iron oxide (E172)	0.120 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*.

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*.

5. 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.

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 and cats

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 and cats, according to the following table:

Bodyweight (kg)	Clavaseptin 62.5 mg - Dogs and Cats 1 tablet per 5 kg bodyweight every 12 hours
[1.0 - 2.5]	½
[2.6 - 5.0]	1
[5.1 - 7.5]	1 ½
[7.6 - 10.0]	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.

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 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.

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.

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, 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.

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 10,100, 250, 500 tablets.
Not all pack sizes may be marketed.

Approved 05 February 2020