ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 750 mg palatable tablets for dogs

Amoxicillin/Clavulanic acid

2. STATEMENT OF ACTIVE SUBSTANCES

Amoxicillin (as amoxicillin trihydrate)…….……. 600 mg
Clavulanic acid (as potassium clavulanate, diluted)…….....150 mg

Excipients
Iron oxide, brown (E172)……..……..……1.43 mg

3. PHARMACEUTICAL FORM

Tablet
Oblong, off-white to brownish speckled, scored tablets of about 24 mm. Tablet can be divided into four equal parts.

4. PACKAGE SIZE

10, 100, 250, 600 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}
Termin ważności (EXP)

11. SPECIAL STORAGE CONDITIONS

Shelf life after first opening the immediate packaging: 48 hours.
Return any part of tablet to the opened blister and use within 48 hours.

12. SPECIFIC 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(S)

Vm 08007/5010

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 750 mg tablets
Amoxicillin 600 mg
Clavulanic acid 150 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 750 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 and manufacturer responsible for batch release:
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

Manufacturer responsible for batch release:
VETOQUINOL SA
MAGNY-VERNOIS
F-70200 LURE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 750 mg palatable tablets for dogs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each tablet contains:

Amoxicillin (as amoxicillin trihydrate)…….600 mg
Clavulanic acid (as potassium clavulanate, diluted) …….150 mg

Excipients
Iron oxide, brown (E172)……..…1.43 mg

Oblong, off-white to brownish speckled, scored tablets of about 24 mm. Tablet can be divided into four equal parts.

4. INDICATION

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 known 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

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For oral use.
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 60 kg body weight every 12 h, according to the following table:

Bodyweight (kg)	Number of tablets twice daily
[> 20 - 30]	½
[30.1 - 45]	3/4
[45.1 - 60]	1
[60.1 - 75]	1 ¼
[75.1 - 90]	1 ½

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

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Shelf life after first opening the immediate packaging: 48 hours.
Return any part of tablet to the opened blister -pack and use within 48 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 WARNINGS

Special precautions for use in animals:

In animals with impaired liver and kidney function, the use of the product should be subject to a benefit/risk 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.
Use of the product should be in accordance with official, national and regional antimicrobial policies.

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.
Narrow spectrum antibacterial therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
Do not use in cases of bacteria sensitive to narrow spectrum penicillins or to amoxicillin as a single substance.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

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.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure, taking all recommended precautions.
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
Accidental ingestion of the product by a child may be harmful.
To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.
In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.

Pregnancy and lactation.
The safety of the veterinary medicinal 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 according to 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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Presentation

Aluminium (oPA/Alu/PE)/Aluminium blister with 10 tablets/blister
Cardboard box: Pack-sizes of 10, 100, 250, and 600 tablets. Not all pack sizes may be marketed.

Approved 09 May 2022