ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 50 mg Palatable tablets for dogs and cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Amoxicillin.....40 mg
(Corresponding to amoxicillin trihydrate)…….45,91 mg
Clavulanic acid.....10 mg
(Corresponding to potassium clavulanate).....11,91 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Not applicable.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Shelf life after first opening the immediate packaging: 16 hours.
Return any halved tablet to the opened blister-pack and use within 16 hours.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA

14. MARKETING AUTHORISATION NUMBERS

Vm 06462/3001

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 50 mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Amoxicillin 40 mg
Clavulanic acid 10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Clavaseptin 50 mg Palatable tablets for dogs and cats

2. Composition

Each tablet contains:

Active substances:
Amoxicillin.....40 mg
(Corresponding to amoxicillin trihydrate)……45,91 mg
Clavulanic acid..... 10 mg
(Corresponding to potassium clavulanate)….11,91 mg

Excipients:
Iron oxide, brown (E172) ……..….0,095 mg

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

3. Target species

Dogs, and cats

4. Indications for use

In dogs: treatment of infections caused by bacteria susceptible to amoxicillin in combination with clavulanic acid (including beta-lactamase producing strains), in particular:

- Skin infections (including deep and superficial pyodermas, wounds, abscesses) caused by *Staphylococcus* spp, *Streptococcus* spp and *Pasteurella* spp.
- Respiratory tract infections (sinusitis, rhino-tracheitis, bronchopneumonia) caused by *Staphylococcus* spp, and *E. coli*.
- Infections of the oral cavity (mucous membranes) caused by *Streptococcus* spp, and *Pasteurella* spp.
- Urinary tract infections (nephritis, cystitis) caused by, *E. coli*, *Klebsiella* spp and *Proteus mirabilis.*
- Digestive tract infections, especially gastroenteritis caused by *E. coli.*

In cats: treatment of infections caused by bacteria susceptible to amoxicillin in combination with clavulanic acid (including beta-lactamase producing strains), in particular:

- Skin infections (including deep and superficial pyodermas, wounds, abscesses) caused by *Staphylococcus* spp, *Streptococcus* spp and *Pasteurella* spp.
- Respiratory tract infections (sinusitis, rhino-tracheitis, bronchopneumonia) caused by *Staphylococcus* spp, and *E. coli*.

- Infections of the oral cavity (mucous membranes) caused by *Streptococcus* spp, and *Pasteurella* spp.
- Urinary tract infections (nephritis, cystitis) caused by, *E. coli, Pasteurella* spp, *Klebsiella* spp and *Proteus mirabilis.*
- Digestive tract infections, especially gastroenteritis caused by *E. 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 or other small herbivores.
Do not use in animals with serious dysfunction of the kidneys accompanied by anuria or oliguria.
Do not administer to horses and ruminating animals.

6. Special warnings

Special warnings:
Cross-resistance has been shown between amoxicillin/clavulanic acid and β-lactam antibiotics. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to βlactam antibiotics because its effectiveness may be reduced.
Methicillin resistant *S. aureus* (MRSA) and methicillin resistant *S. pseudintermedius* (MRSP) have been isolated in cats and dogs with proportion of resistance that varies across EU countries.
Do not use in cases of known resistance to the combination of amoxicillin and clavulanic acid.
Do not use in cases of suspected or confirmed MRSA/MRSP infections, as isolates should be considered resistant to all β-lactam including amoxicillin/clavulanic acid combination.
High resistances (up to 100%) have been reported in *E. coli* isolates from skin and soft tissue infections in dogs.

Special precautions for safe use in the target species:

In animals with impaired liver and kidney function, the use of the veterinary medicinal product should be subject to a benefit/risk evaluation by the veterinary surgeon and the posology evaluated carefully.
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s).
If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

Aminopenicillins in combination with beta-lactamase inhibitors are in AMEG category „C". An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Narrow spectrum antibiotic 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.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.
The potential for allergic cross-reactivity with other penicillins should be considered.

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 veterinary medicinal product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this veterinary medicinal 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 veterinary medicinal 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 immediately 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 harmful effects to the foetus or the mother. Use only according to 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.
Penicillins may increase the effect of aminoglycosides.

Overdose:

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.

Major incompatibilities:

None known.

7. Adverse events

Dogs and cats.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1], Diarrhoea.[1] Hypersensitivity reaction (Allergic skin reactions[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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the its local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Oral use.

The recommended dose of the veterinary medicinal product is 10 mg amoxicillin /2.5 mg clavulanic acid per kg body weight twice a day, i.e. 1 tablet per 4 kg bodyweight every 12 h, for 5 to 7 days, 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 cases, the dose can be doubled at the discretion of the responsible veterinarian.

Duration of the treatment:
For all indications, a treatment of 5 to 7 days is sufficient in the majority of cases. For chronic or recurrent cases, it may be necessary to continue treatment for 2 to 4 weeks.

9. Advice on correct administration

To ensure the correct dosage, body weight should be determined as accurately as possible.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
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 precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06462/3001

Aluminium/aluminium (oPA/Alu/PE) 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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Vetoquinol SA
34 Rue de Chene Sainte-Anne
Magny-Vernois,
70200 Lure
France

Manufacturer responsible for batch release: Vetoquinol S.A Magny-Vernois 70200 Lure, France.

Gavin Hall
Approved: 25 July 2025