PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavipet 40 mg/10 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains: 40 mg amoxicillin and 10 mg clavulanic acid.

3. PACKAGE SIZE

10 tablets
20 tablets
100 tablets
500 tablets

4. TARGET SPECIES

Cats and dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Any unused half tablets should be returned to the blister pack and used within 12 hours.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Store in the original package in order to protect from light and moisture

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

KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/5118
Vm 01656/3118

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavipet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

40 mg/10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavipet 40 mg/10 mg chewable tablets for cats and dogs

2. COMPOSITION

Each chewable tablet contains:

Active substances:

Amoxicillin (as amoxicillin trihydrate)	40 mg
Clavulanic acid (as potassium clavulanate, diluted)	10 mg

Pink mottled tablets, round, with a break line on one side.
The tablet can be divided into halves.

3. TARGET SPECIES

Cats and dogs.

4. INDICATIONS FOR USE

Dogs:
For the treatment of
- Skin infections (including deep and superficial pyoderma).
- Soft tissue infections (including anal sacculitis and abscesses).
- Urinary tract infections.
- Respiratory infections.
- Intestinal infections.
- Periodontal infections in addition to mechanical or surgical periodontal therapy.

Cats:
For the treatment of
- Skin infections (including superficial pyoderma).
- Soft tissue infections (including abscesses).
- Urinary tract infections.
- Respiratory infections.
- Intestinal infections.
- Periodontal infections in addition to mechanical or surgical periodontal therapy.

5. CONTRAINDICATIONS

Do not administer to gerbils, guinea pigs, hamsters, rabbits and chinchillas. Do not use in horses and ruminants.
Do not use in cases of serious dysfunction of the kidneys accompanied by anuria and oliguria.

Do not use in cases of hypersensitivity to penicillins or other substances of the β-lactam group or to any excipients.
Do not use in cases of known resistance to the combination of amoxicillin and clavulanic acid.

6. SPECIAL WARNINGS

Special warnings:
Cross-resistance has been shown between amoxicillin/clavulanic acid and other antibiotics belonging to the beta-lactam group. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to other antimicrobials in the beta-lactam group because its effectiveness may be reduced.
When susceptibility testing has shown resistance to sole beta-lactam, but susceptibility to combination of amoxicillin/clavulanic acid has been confirmed, treatment with the veterinary medicinal product might nevertheless be considered.
Do not use in cases of suspected or confirmed methicillin resistant *S. aureus* (MRSA) and methicillin resistant *S. pseudintermedius* (MRSP) infections, as such isolates should be considered resistant to all beta-lactams including amoxicillin/clavulanic acid combinations.
The veterinary medicinal product has no effect against infections caused by *Pseudomonas* spp. due to its inherent resistance.

Special precautions for safe use in the target species:
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.
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.
Pharmacokinetic of the active substances in the target tissue might be considered as well.
The routine use of systemic antibiotics for intestinal infections is not recommended. Oral treatment with antibiotics can result in disturbance of gastrointestinal flora, especially in case of long-term treatment.
In case of renal or hepatic insufficiency, the use of the veterinary medicinal product should be subject to a benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may cause hypersensitivity (allergy) following 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.
People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product. Personal protective equipment consisting of gloves should be worn when handling this veterinary medicinal product to avoid skin contact.
If you develop symptoms such as a skin rash and persistent eye irritation after exposure to the veterinary medicinal product, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.
Wash hands after use.
To prevent children from accessing the veterinary medicinal product, only the required number of tablets should be removed from the blister pack and only when required. Store any unused portion of the tablet in the opened blister pack and return it into the carton immediately after use. The carton should be stored out of the sight and reach of children. 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.
In laboratory studies (rats and mouse) signs of embryotoxicity or teratogenicity could only be detected at high doses.
Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Chloramphenicol, macrolides, sulfonamides and tetracyclines may inhibit the antibacterial effect of penicillins because of the rapid onset of bacteriostatic action.
Penicillins may increase the effect of aminoglycosides.

Overdose:
Doses up to 40 mg amoxicillin and 10 mg clavulanic acid/kg and 60 mg amoxicillin and 15 mg clavulanic acid/kg administered twice daily for 5 days were tolerated well in young dogs and young cats respectively.
No adverse events associated with overdoses other than those listed in section “Adverse events” were detected in the respective studies (for information on symptomatic treatment see also section on adverse events).
Due to the neurotoxicity of penicillins, overdosing might result in central nervous system symptoms and convulsions. In these cases, treatment with the veterinary medicinal product should be discontinued immediately and symptomatic treatment should be initiated.

7. ADVERSE EVENTS

Cats and dogs:

Common (1 to 10 animals / 100 animals treated):	gastrointestinal disorder[1] (e.g. vomiting, diarrhoea)
Uncommon (1 to 10 animals / 1 000 animals treated):	hypersalivation anorexia[1, 2], lethargy
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	hypersensitivity reaction[3] (e.g. allergic skin reaction, anaphylaxis)

[1] Depending on the severity of the adverse event treatment should be discontinued and symptomatic treatment initiated based on the benefit-risk assessment by the responsible veterinarian.
[2] Very rare (<1 animal / 10 000 animals treated, including isolated reports) in cats.
[3] May be serious. Immediate discontinuation of the veterinary medicinal product is required. Countermeasures to be taken in case of an allergic reaction:

- anaphylaxis: administer epinephrine (adrenaline) and glucocorticoids.
- allergic skin reactions: administer antihistamines and/or glucocorticoids.

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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

Administration: for oral use.

Dosage rate and frequency: 10 mg amoxicillin and 2.5 mg clavulanic acid/kg body weight (i.e. 12.5 mg of combined active substances per kg bodyweight), every 12 hours.

In refractory respiratory tract infections, the dose can be doubled to 20 mg amoxicillin and 5 mg clavulanic acid/kg body weight every 12 hours and the treatment can be prolonged for up to 10 days.

The following table is intended as a guide to dispensing the veterinary medicinal product at the recommended dose rate:

Bodyweight (kg)	Number of tablets per dose twice daily
1.0-2.0	½
2.1-4.0	1
4.1-6.0	1 ½
6.1-8.0	2
>8.0	Use 200 mg/50 mg or 400 mg/100 mg tablet(s)

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

Duration of treatment:
The majority of routine cases respond to between 5 and 7 days therapy. In chronic cases, a longer course of therapy is recommended.
Based on clinical trials, the following treatment durations are recommended:
Chronic skin infections, 10–20 days.
Chronic cystitis, 10–28 days.

9. ADVICE ON CORRECT ADMINISTRATION

If the animal does not accept the tablet from hand or bowl, then the tablets may be crumbled and added to a little food and fed immediately.

10. WITHDRAWAL PERIODS

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 in order to protect from light and moisture.

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

Any unused half tablets should be returned to the blister pack and used within 12 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

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 01656/5118
Vm 01656/3118

Blister contains 10 tablets. Carton contains 10, 20, 100 or 500 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:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

Manufacturer responsible for batch release:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

Local representatives and contact details to report suspected adverse reactions:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
info.uk@krka.biz

17. OTHER INFORMATION

POM-V

Gavin Hall

Approved 24 July 2026