PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavipet 400 mg/100 mg chewable tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each chewable tablet contains: 400 mg amoxicillin and 100 mg clavulanic acid.

3. PACKAGE SIZE

12 tablets
60 tablets
300 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.
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 01656/5120

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

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

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V (‘Veterinary medicinal product subject to prescription’)

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavipet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

400 mg/100 mg
amoxicillin/clavulanic acid

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavipet 400 mg/100 mg chewable tablets for dogs

2. COMPOSITION

Each chewable tablet contains:

Active substances:

Amoxicillin (as amoxicillin trihydrate)	400 mg
Clavulanic acid (as potassium clavulanate, diluted)	100 mg

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

3. TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

For the treatment of infections caused by bacteria susceptible to amoxicillin and clavulanic acid including: skin disease (including deep and superficial pyodermas); soft tissue infections (abscesses and anal sacculitis); dental infections (e.g. gingivitis); urinary tract infections; respiratory disease (involving upper and lower respiratory tract); enteritis.

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 for each target species
This product is not indicated for cases involving *Pseudomonas* spp.

Special precautions for use in animals:
Use of the 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 farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

A narrow spectrum antibiotic therapy or 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.Use of the product deviating from the instructions given in the package leaflet may increase the prevalence of bacteria resistant to amoxicillin/clavulanic acid and may decrease the effectiveness of treatment with other penicillins, due to the potential for crossresistance.
A trend in resistance of *E. coli* is reported, including multidrug-resistant *E. coli*.
In animals with hepatic and renal dysfunction, the dosing regimen should be carefully evaluated and the use of the product based on a risk/benefit evaluation by the veterinary surgeon.
Caution is advised in the use of the product in small herbivores, alongside those listed in section 5. Contraindications.
The chewable 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 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 care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. 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 avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space, inserted back into the outer packaging and kept in a safe place out of the sight and reach of children.

Pregnancy and lactation:
Laboratory studies in rats and mice have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.
The safety of the product has not been assessed in pregnant and lactating bitches.
In pregnant and lactating animals, 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 (symptoms, emergency procedures, antidotes):
Mild gastrointestinal symptoms (diarrhoea, nausea and vomiting) may occur after overdose of the product and symptomatic treatment should be initiated when necessary.

Incompatibilities:
None known.

7. ADVERSE EVENTS

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (allergic skin reaction, anaphylaxis)* Diarrhoea**, Vomiting** Anorexia**

*Administration should be discontinued and a symptomatic treatment given.
**Treatment may be discontinued depending on the severity of the undesirable effects and a benefit/risk evaluation by the veterinary surgeon.

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><the 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, ROUTE(S) 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), twice daily (corresponding to 25 mg of combined active substances per kg per day).

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

Bodyweight (kg)	Number of tablets per dose twice daily
≤30.0	Use 40 mg/10 mg or 200 mg/50 mg tablet(s)
30.1-40.0	1
40.1-60.0	1 ½
60.1-80.0	2

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Duration of therapy: The majority of routine cases respond to between 5 and 7 days therapy. In chronic cases, a longer course of therapy is recommended. In such circumstances, overall treatment length must be at the clinician's discretion but should be long enough to ensure complete resolution of the bacterial disease.

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 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 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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Blister contains 6 tablets. Carton contains 12, 60 or 300 tablets.
Not all pack sizes may be marketed.

Vm 01656/5120

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

17. OTHER INFORMATION

POM-V ('Veterinary medicinal product subject to prescription')

For animal treatment only.

Gavin Hall

Approved 18 October 2024