ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cladaxxa 200 mg/50 mg chewable tablets for cats and dogs
Amoxicillin/Clavulanic acid

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:
200 mg amoxicillin and 50 mg clavulanic acid.

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

10 tablets
20 tablets
100 tablets
500 tablets

5. TARGET SPECIES

Cats and dogs

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING, IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}
Any unused half tablets should be returned to the blister pack and used within 12 hours.

11. SPECIAL STORAGE CONDITIONS

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

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

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

16. MARKETING AUTHORISATION NUMBER

Vm 01656/4021

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cladaxxa 200 mg/50 mg chewable tablets for cats and dogs
Amoxicillin/Clavulanic acid
Amoxicillinum/Acidum clavulanicum (for multilingual packaging)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

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:
Cladaxxa 200 mg/50 mg chewable tablets for cats and dogs

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:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cladaxxa 200 mg/50 mg chewable tablets for cats and dogs

Amoxicillin/Clavulanic acid

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

Each chewable tablet contains:

Active substances:

Amoxicillin (as amoxicillin trihydrate)	200 mg
Clavulanic acid (as potassium clavulanate, diluted)	50 mg

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

4. INDICATION

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. ADVERSE REACTIONS

Very rarely, hypersensitivity reactions to penicillins may occur in treated animals; in these cases, administration should be discontinued and a symptomatic treatment given.
Very rarely, gastro-intestinal disturbances (diarrhoea, vomiting, …) may occur after administration of the product. Treatment may be discontinued depending on the severity of the undesirable effects and a benefit/risk evaluation by the veterinary surgeon.

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

Cats and dogs.

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
≤8.0	Use 40 mg/10 mg tablet(s)
8.1-10.0	½
10.1-20.0	1
20.1-30.0	1 ½
30.1-40.0	2
>40.0	Use 400 mg/100 mg tablet(s)

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 WARNINGS

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

Special precautions for use in animals:
Whenever possible, the amoxicillin/clavulanic acid combination should only be used based on susceptibility testing.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
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 in small herbivores other than those in section 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 and queens.
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.

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

November 2023

15. OTHER INFORMATION

Blister contains 10 tablets. Carton contains 10, 20, 100 or 500 tablets.

Not all pack sizes may be marketed.

Approved 22 December 2023