**Veterinary Medicinal Product**

Kesium 500 mg / 125 mg Chewable tablets for dogs

**PART I B**

**A - LABELLING**

Pharmaceutical Form

Chewable Tablet

Veterinary Medicinal product

Kesium 500 mg / 125 mg Chewable tablets for dogs

**PART IB**

**A – LABELLING – "OUTER PACKAGE"**

Pharmaceutical form

Chewable Tablet

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kesium 500 mg / 125 mg Chewable tablets for dogs

Amoxicillin (as amoxicillin trihydrate)
Clavulanic acid (as potassium clavulanate)

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
**Active substance:**

| | |
|---|---|
| Amoxicillin (as amoxicillin trihydrate) | 500.00 mg |
| Clavulanic acid (as potassium clavulanate) | 125.00 mg |

## 3. PHARMACEUTICAL FORM

Chewable tablet
Clover-shaped scored beige tablet. The tablet can be divided into four equal parts.

## 4. PACKAGE SIZE

Cardboard box of 6 tablets
Cardboard box of 12 tablets
Cardboard box of 96 tablets
Cardboard box of 144 tablets
Cardboard box of 240 tablets

## 5. TARGET SPECIES

Dogs

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP {month/year}
Any divided tablet portions remaining after 36 hours should be discarded

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Divided tablets should be stored in the blister pack

## 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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

## 16. MARKETING AUTHORISATION NUMBER

Vm 15052/4135

## 17. MANUFACTURER'S BATCH NUMBER

Batch:

Veterinary Medicinal product

Kesium 500 mg / 125 mg Chewable tablets for dogs

**PART IB**

**A – LABELLING – BLISTER**

Pharmaceutical form

Chewable Tablet

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kesium 500 mg / 125 mg Chewable tablets for dogs

Amoxicillin (as amoxicillin trihydrate)
Clavulanic acid (as potassium clavulanate)

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva logo

## 3. EXPIRY DATE

EXP {month/year}

## 4. BATCH NUMBER

Batch:

## 5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

**Veterinary Medicinal product**

Kesium 500 mg / 125 mg Chewable tablets for dogs

**PART IB**

**B – PACKAGE LEAFLET**

**Pharmaceutical form**

Chewable Tablet

# PACKAGE LEAFLET

Kesium 500 mg / 125 mg Chewable tablets for 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:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 LOUVERNE
FRANCE

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kesium 500 mg / 125 mg Chewable tablets for dogs

Amoxicillin (as amoxicillin trihydrate)
Clavulanic acid (as potassium clavulanate)

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

Each tablet contains:
**Active substance:**

| | |
|---|---|
| Amoxicillin (as amoxicillin trihydrate) | 500.00 mg |
| Clavulanic acid (as potassium clavulanate) | 125.00 mg |

Chewable tablet
Clover-shaped scored beige tablet. The tablet can be divided into four equal parts.

## 4. INDICATION(S)

For the treatment of the following infections caused by β-lactamase producing strains of bacteria sensitive to amoxicillin in combination with clavulanic acid and where clinical experience and/or sensitivity testing indicates the product as the drug of choice:

- Skin infections (including superficial and deep pyodermas) associated with *Staphylococcus* spp..
- Urinary tract infections associated with *Staphylococcus* spp., *Streptococcus* spp.*, Escherichia coli* and *Proteus mirabilis*.
- Respiratory tract infections associated with *Staphylococcus spp., Streptococcus spp. and Pasteurella* spp..
- Digestive tract infections associated with *Escherichia coli*.
- Infections of the oral cavity (mucous membrane) associated with *Pasteurella* spp.*, Streptococcus* spp.*, Escherichia coli.*

## 5. CONTRAINDICATIONS

Do not use in animals with hypersensitivity to penicillins or other substances of the β-lactam group or to any excipients.
Do not use in animals with serious dysfunction of the kidneys accompanied by anuria and oliguria.

Do not administer to gerbils, guinea pigs, hamsters, rabbits and chinchillas. Do not use in horses and ruminating animals.
Do not use where resistance to this combination is known to occur.

## 6. ADVERSE REACTIONS

Mild gastrointestinal signs (diarrhoea, and 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.

Allergic reactions (skin reactions, anaphylaxis) may occasionally occur. 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(S) AND METHOD OF ADMINISTRATION

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 50 kg body weight every 12 h, according to the following table:

| Body weight (kg) | Number of tablets to be administered twice daily |
|---|---|
| > 9 to 12.5 | ¼ |
| 12.6 to 20 | Use the 250 mg |
| 20.1 to 25 | ½ |
| 25.1 to 37.5 | ¾ |
| 37.6 to 50 | 1 |
| 50.1 to 62.5 | 1¼ |
| 62.6 to 75 | 1½ |

In refractory cases the dose may be doubled to 20 mg of amoxicillin / 5 mg clavulanic acid/kg bodyweight twice daily, at the clinician's discretion.

Duration of therapy
The majority of routine cases respond to 5 – 7 days of therapy.
In chronic cases, a longer case 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.

To ensure the correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.

## 9. ADVICE ON CORRECT ADMINISTRATION

The chewable tablets are flavoured and are accepted by a majority of dogs. The chewable tablets can be administered directly into the mouth of the animals or added to a small quantity of food.
Instruction on how to divide the tablet: Put the tablet on an even surface, with its scored side facing down (convex face up). With the tip of the forefinger, exert slight vertical pressure on the middle of the tablet to break it along its width into halves. Then, in order to obtain quarters, exert slight pressure on the middle of one half with the forefinger to break it into two parts.

## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Divided tablets should be stored in the blister pack

Any divided tablet portions remaining after 36 hours should be discarded
Do not use after the expiry date stated on the blister and the carton.

## 12. SPECIAL WARNING(S)

**Special precautions for use in animals**
Official, national and regional antimicrobial policies with respect to the use of broad-spectrum antibiotics should be taken into account.
Do not use in case of bacteria sensitive to narrow spectrum penicillins or to amoxicillin as single substance.
It is advised that upon initiating therapy appropriate sensitivity testing is performed and that therapy is continued only after susceptibility to the combination has been established.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the amoxicillin/clavulanate, and may decrease the effectiveness of treatment with β-lactam antibiotics
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 the section "Contraindications".

The potential for allergic cross-reactions with other penicillin derivates and cephalosporins should be considered.
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 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 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.

**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)**
In case of overdose diarrhoea, allergic reactions or further symptoms like central nervous excitation manifestations or cramps could appear. Symptomatic treatment should be initiated when necessary.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

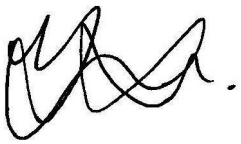
October 2022

## 15. OTHER INFORMATION

Pack sizes:
Cardboard box of 6 tablets
Cardboard box of 12 tablets
Cardboard box of 96 tablets
Cardboard box of 144 tablets
Cardboard box of 240 tablets

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 18 October 2022