Ceva Animal Health Ltd

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Kesium® 40mg/10mg & 50mg/12.5mg chewable tablets for cats & dogs and Kesium® 200mg/50mg, 400mg/100mg & 500mg/125mg chewable tablets for dogs

Species: Cats, Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Oral preparations: Tablets

Active ingredient: Amoxicillin Trihydrate, Clavulanic Acid

Product: Kesium® 40mg/10mg & 50mg/12.5mg chewable tablets for cats & dogs and Kesium® 200mg/50mg, 400mg/100mg & 500mg/125mg chewable tablets for dogs

Product index: Kesium

Incorporating:

Qualitative and quantitative composition

Active substance:

Each Kesium 40mg/10mg tablet contains: Amoxicillin (as amoxicillin trihydrate) 40.00 mg and clavulanic acid (as potassium clavulanate) 10.00 mg

Each Kesium 50mg/12.5mg tablet contains: Amoxicillin (as amoxicillin trihydrate) 50.00 mg and clavulanic acid (as potassium clavulanate) 12.5 mg

Each Kesium 200mg/50mg tablet contains: Amoxicillin (as amoxicillin trihydrate) 200.00 mg and clavulanic acid (as potassium clavulanate) 50.00 mg

Each Kesium 400mg/100mg tablet contains: Amoxicillin (as amoxicillin trihydrate) 400.00 mg and clavulanic acid (as potassium clavulanate) 100 mg

Each Kesium 500mg/125mg tablet contains: Amoxicillin (as amoxicillin trihydrate) 500.00 mg and clavulanic acid (as potassium clavulanate) 125 mg

Excipients:

For the full list of excipients, see Pharmaceutical particulars

NOAH Compendium

Pharmaceutical form

Kesium 40mg/10mg, 50mg/12.5mg and 400mg/100mg tablets are oblong, scored, chewable tablets that can be divided into equal halves.

Kesium 200mg/50mg and 500mg/125mg tablets are clover-shaped, beige, chewable tablets that can be divided into four equal parts.

Clinical particulars

Target species

Dogs and cats.

Indications for use, specifying the target species

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*.

Contraindications

Do not use in animals with known hypersensitivity to penicillins or other susbstances 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.

Special warnings for each target species

None known

Special precautions for use

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 beta-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.

Adverse reactions (frequency and seriousness)

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal signs
	Allergic reaction (e.g.

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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

Laboratory studies in rats and mice have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

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.

Amounts to be administered and administration route

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 and cats, according to the following tables:

Kesium 40mg/10mg chewable tablets for cats and dogs:

Bodyweight (kg)	**Number of 40mg/10mg tablets twice daily**
>1 - 2	½
>2 - 4	1
>4 - 6	1 ½
>6 - 8	2

Kesium 50mg/12.5mg chewable tablets for cats and dogs:

Bodyweight (kg)	**Number of 50mg/12.5mg tablets twice daily**
>1.3 - 2.5	½
>2.6 - 5	1
>5.1 - 7.5	1 ½
>7.6 - 10	2

Kesium 200mg/50mg chewable tablets for dogs:

Bodyweight (kg)	**Number of 200mg/50mg tablets twice daily**
>2.6 - 5.0	1⁄4
>5.1 - 10.0	½
>10.1 - 15.0	3⁄4

>15.1 - 20.0	1
>20.1 - 25.0	1 ¼
>25.1 - 30.0	1 ½
>30.1 - 35.0	1 ¾
>35.1 - 40.0	2

Kesium 400mg/100mg chewable tablets for dogs:

Bodyweight (kg)	**Number of 400mg/100mg tablets twice daily**
>15 - 20	½
>20 - 25	Use Kesium 200mg/50mg tablets
>25 - 40	1
>40 - 60	1 ½
>60 - 80	2

Kesium 500mg/125mg chewable tablets for dogs:

Bodyweight (kg)	**Number of 500mg/125mg tablets twice daily**
>9 - 12.5	¼
12.6 - 20	Use Kesium 200mg/50mg
20.1 - 25	½
25.1 - 37.5	¾
37.6 - 50	1
50.1 - 62.5	1 ¼
62.6 - 75	1 ½

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.

The chewable tablets are flavoured and are accepted by a majority of cats and dogs. The chewable tablets can be administered directly into the mouth of the animals or added to a small quantity of food.

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.

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.

Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

Withdrawal period(s)

Not applicable

Pharmacological particulars

Pharmacotherapeutic group: Beta-lactam antibacterials, penicillins. ATCvet code: QJ01CR02

Pharmacodynamic properties

Amoxicillin is a beta-lactam antibiotic and its structure contains the beta-lactam ring and thiazolidine ring common to all penicillins. Amoxicillin shows activity against susceptible Gram-positive bacteria and Gram-negative bacteria.

Beta-lactam antibiotics prevent the bacterial cell wall from forming by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes, which catalyse cross-linkage of the glycopeptide polymer units that form the cell wall. They exert a bactericidal action but cause lysis of growing cells only.

Clavulanic acid is one of the naturally occurring metabolites of the streptomycete *Streptomyces clavuligerus*. It has a structural similarity to the penicillin nucleus, including possession of a beta-lactam ring. Clavulanic acid is a beta-lactamase inhibitor acting initially competitively but ultimately irreversibly. Clavulanic acid will penetrate the bacterial cell wall binding to both extracellular and intracellular beta-lactamases.

Amoxicillin is susceptible to breakdown by ß-lactamase and therefore combination with an effective ß-lactamase inhibitor (clavulanic acid) extends the range of bacteria against which it is active to include ß-lactamase producing species.

In vitro potentiated amoxicillin is active against a wide range of clinically important aerobic and anaerobic bacteria including:

Gram-positive: *Staphylococcus* spp. (including β-lactamase producing strains), *Streptococcus* spp

Gram-negative: *Escherichia coli* (including most β-lactamase producing strains), *Pasteurella* spp, *Proteus* spp

Resistance is shown among *Enterobacter* spp, *Pseudomonas aeruginosa* and methicillin-resistant *Staphylococcus aureus*.

A trend in resistance of *E. coli* is reported.

Pharmacokinetic properties

After oral administration in dogs, amoxicillin and clavulanic acid are rapidly absorbed. Amoxicillin (pKa 2.8) has a relatively small apparent distribution volume, a low plasma protein binding (34% in dogs) and a short terminal half-life due to active tubular excretion via the kidneys. Following absorption the highest concentrations are found in the kidneys (urine) and the bile and then in liver, lungs, heart and spleen. The distribution of amoxicillin to the cerebrospinal fluid is low unless the meninges are inflamed.

Clavulanic acid (pKa 2.7) is also well-absorbed following oral administration. The penetration to the cerebrospinal fluid is poor. The plasma protein binding is approximately 25% and the elimination half-life is short. Clavulanic acid is mainly eliminated by renal excretion (unchanged in urine).

After single oral administration of 17 mg/kg amoxicillin and 4.3 mg/kg clavulanic acid in dogs:

-The maximal plasma concentration (Cmax) of amoxicillin (8.6 µg/mL) was observed 1.5 hour following administration.

-The maximal plasma concentration (Cmax) of clavulanic acid (4.9 µg/mL) was observed 54 minutes following administration.

After single oral administration of 13 mg/kg amoxicillin and 3.15 mg/kg clavulanic acid in cats:

-The maximal plasma concentration (Cmax) of amoxicillin (9.3 µg/mL) was observed 2 hours following administration.

-The maximal plasma concentration (Cmax) of clavulanic acid (4.1 µg/mL) was observed 50 minutes following administration

Pharmaceutical particulars

List of Excipient(s)

Pig liver powder, Yeast, Crospovidone (type A), Povidone K 25, Hypromellose, Microcrystalline cellulose, Silica, colloidal anhydrous, Magnesium stearate

Incompatibilities

Not applicable

Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:

Kesium 40mg/10mg: 2 years.

Kesium 50mg/12.5mg: 21 months.

Kesium 200mg/50mg, 400mg/100mg, 500mg/125mg: 3 years.

Any divided tablet portions of Kesium 40mg/10mg, 50mg/12.5mg and 400mg/100mg remaining after 12 hours should be discarded.

Any divided tablet portions of Kesium 200mg/50mg and 500mg/125mg remaining after 36 hours should be discarded.

Special precautions for storage

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

Nature and composition of immediate packaging

(PA-AL-PVC - aluminium heat sealed)

Kesium 40mg/10mg and 50mg/12.5mg tablets, containing 10 tablets per blister:

Cardboard box with 1 blister of 10 tablets; Cardboard box with 2 blisters of 10 tablets; Cardboard box with 4 blisters of 10 tablets; Cardboard box with 6 blisters of 10 tablets; Cardboard box with 8 blisters of 10 tablets; Cardboard box with 10 blisters of 10 tablets; Cardboard box with 24 blisters of 10 tablets.

Kesium 200mg/50mg tablet, containing 8 tablets per blister:

Cardboard box with 1 blister of 8 tablets; Cardboard box with 2 blisters of 8 tablets; Cardboard box with 4 blisters of 8 tablets; Cardboard box with 6 blisters of 8 tablets; Cardboard box with 8 blisters of 8 tablets; Cardboard box with 10 blisters of 8 tablets; Cardboard box with 12 blisters of 8 tablets; Cardboard box with 30 blisters of 8 tablets.

Kesium 400mg/100mg tablet, containing 6 tablets per blister:

Cardboard box with 1 blister of 6 tablets; Cardboard box with 2 blisters of 6 tablets; Cardboard box with 4 blisters of 6 tablets; Cardboard box with 6 blisters of 6 tablets; Cardboard box with 8 blisters of 6 tablets; Cardboard box with 10 blisters of 6 tablets; Cardboard box with 12 blisters of 6 tablets; Cardboard box with 14 blisters of 6 tablets; Cardboard box with 16 blisters of 6 tablets; Cardboard box with 40 blisters of 6 tablets.

Kesium 400mg/100mg containing 4 tablets per blister:

Cardboard box with 3 blisters of 4 tablets; Cardboard box with 6 blisters of 4 tablets; Cardboard box with 9 blisters of 4 tablets; Cardboard box with 12 blisters of 4 tablets; Cardboard box with 15 blisters of 4 tablets; Cardboard box with 18 blisters of 4 tablets; Cardboard box with 21 blisters of 4 tablets; Cardboard box with 24 blisters of 4 tablets; Cardboard box with 60 blisters of 4 tablets.

Kesium 500mg/125mg tablet, containing 6 tablets per blister:

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

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

Marketing Authorisation Number

40 mg/10 mg:

GB Vm 14966/5073

NI Vm 14966/3072

50 mg/ 12.5 mg:

GB Vm 14966/5066

NI Vm 14966/3065

200 mg / 50 mg:

GB Vm 14966/5072

NI Vm 14966/3071

400 mg / 100 mg:

GB Vm 14966/5074

NI Vm 14966/3073

500 mg / 125 mg:

GB Vm 14966/5067

NI Vm 14966/3066

Significant changes

Date of the first authorisation or date of renewal

Kesium 40mg/10mg tablets, 50mg/12.5mg tablets, 200mg/50mg tablets and 400mg/100mg tablets: 5th October 2011

Kesium 500mg/125mg tablets: 24th October 2013

Date of revision of the text

October 2025

Any other information

Nil

Legal category

Legal category:POM-V

GTIN

GTIN description: Kesium 40mg/10mg 24x10T

GTIN:03411113069643

GTIN description: Kesium 50mg/12.5mg 24x10T

GTIN:03411113069728

GTIN description: Kesium 200mg/50mg 30x8T

GTIN:03411113069629

GTIN description: Kesium 400mg/100mg 16x6T

GTIN:03411113069650

GTIN description: Kesium 500mg/125mg 16x6T

GTIN:03411113070137