PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kesium 400 / 100 mg Chewable tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Active substance:

Amoxicillin (as amoxicillin trihydrate)	400.00 mg
Clavulanic acid (as potassium clavulanate)	150.00 mg

3. PACKAGE SIZE

1 x 6 tablets
2 x 6 tablets
4 x 6 tablets
6 x 6 tablets
8 x 6 tablets
10 x 6 tablets
12 x 6 tablets
14 x 6 tablets
16 x 6 tablets
40 x 6 tablets
80 x 6 tablets
3 x 4 tablets
6 x 4 tablets
9 x 4 tablets
12 x 4 tablets
15 x 4 tablets
18 x 4 tablets
21 x 4 tablets
24 x 4 tablets
60 x 4 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {mm/yyyy}
Any divided tablet portions remaining after 12 hours should be discarded.

9. SPECIAL STORAGE PRECAUTIONS

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

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

Ceva Animal Health Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/5069
Vm 15052/3034

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (BLISTERS)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kesium 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

400 mg of amoxicillin (as amoxicillin trihydrate)/ 100 mg of clavulanic acid (as potassium clavulanate)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Kesium 400 mg/ 100 mg Chewable tablets for dogs

2. Composition

Each tablet contains:
Active substances:
Amoxicillin (as amoxicillin trihydrate 400 mg
Clavulanic acid (as potassium clavulanate) 100 mg

Oval scored beige chewable tablet. The tablets can be divided into equal halves.

3. Target species

Dogs

4. Indications for use

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 veterinary medicinal 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* and *Escherichia coli.*

5. Contraindications

Do not use in cases of hypersensitivity to penicillins, to 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.

6. Special warnings

Special precautions for safe use in the target species

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 veterinary medicinal 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 veterinary medicinal 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.

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.

Overdose:
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.

7. Adverse events

Dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal signs (e.g. diarrhoea or vomiting)[1] Allergic reaction (e.g. allergic skin reaction, anaphylaxis)[2]

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

8. Dosage for each species, routes

Oral use
The recommended dose of the veterinary medicinal 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 40 kg body weight every 12 h, according to the following table:

Body weight (kg)	Number of tablets twice daily
> 15 to 20	½
> 20 to 25	Use Kesium 250mg
> 25 to 40.0	1
> 40 to 60	1 ½
> 60 to 80	2

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.

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.

10. Withdrawal periods

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 12 hours should be discarded
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.

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 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 15052/5069
Vm 15052/3034

Pack sizes:
(PA-AL-PVC – aluminium heat sealed) containing 4 or 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.
Cardboard box with 80 blisters of 6 tablets.

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.

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 and contact details to report suspected adverse reactions:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel: 01628 334 056
Email for the reporting of adverse events: technicalandpvuk-group@ceva.com

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

17. Other information

POM-V

Veterinary Medicinal product subject to prescription
For animal treatment only

Approved 14 January 2025
Gavin Hall