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Clavaseptin 50 mg and 62.5 mg Palatable Tablets for Dogs and Cats, Clavaseptin 250 mg, 500 mg & 750 mg Palatable Tablets for Dogs

Species: Cats, Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Oral preparations: Tablets

Active ingredient: Amoxicillin Trihydrate, Clavulanic Acid

Product: Clavaseptin 50 mg Palatable Tablets for Dogs and Cats,
Clavaseptin 62.5 mg Palatable Tablets for Dogs and Cats,
Clavaseptin 250 mg Palatable Tablets for Dogs
Clavaseptin 500 mg Palatable Tablets for Dogs
Clavaseptin 750 mg Palatable Tablets for Dogs

Product index: Clavaseptin

Incorporating: Clavaseptin 50 mg Palatable Tablets for Dogs and Cats,
Clavaseptin 62.5 mg Palatable Tablets for Dogs and Cats,
Clavaseptin 250 mg Palatable Tablets for Dogs
Clavaseptin 500 mg Palatable Tablets for Dogs
Clavaseptin 750 mg Palatable Tablets for Dogs

Presentation

Five tablet strengths are available:

Clavaseptin 50 mg Palatable Tablets containing 40mg amoxicillin (as trihydrate) and 10mg clavulanic acid (as potassium salt). For use in cats and dogs.

Clavaseptin 62.5 mg Palatable Tablets containing 50 mg amoxicillin (as trihydrate) and 12.5 mg clavulanic acid (as potassium salt). For use in cats and dogs.

Clavaseptin 250 mg Palatable Tablets containing 200 mg amoxicillin (as trihydrate) and 50mg clavulanic acid (as potassium salt). For use in dogs.

Clavaseptin 500 mg Palatable Tablets containing 400mg amoxicillin (as trihydrate) and 100mg clavulanic acid (as potassium salt). For use in dogs.

Clavaseptin 750 mg Palatable Tablets containing 600mg amoxicillin (as trihydrate) and 150mg clavulanic acid (as potassium salt). For use in dogs.

Excipient: Brown Iron Oxide (E172)

Uses

In dogs: treatment or adjunctive treatment of periodontal infections caused by bacteria susceptible to amoxicillin in combination with clavulanic acid i.e. *Pasteurella* spp, *Streptococcus* spp and *Escherichia coli.*

In cats: treatment of skin infections (including wounds and abscesses) caused by bacteria susceptible to amoxicillin in combination with clavulanic acid i.e. *Pasteurella* spp, *Staphylococcus* spp, *Streptococcus* spp and *Escherichia coli.*

Dosage and administration

For oral administration.

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

The recommended dose of Clavaseptin Palatable Tablets is 10 mg amoxicillin/2.5mg clavulanic acid/kg twice daily by the oral route in dogs and cats.

In severe infections, the dose may be doubled to 20 mg amoxicillin/5 mg clavulanic acid/kg body weight twice daily.

Duration of treatment:

- 7 days for the treatment of periodontal infections in dogs

- 7 to 14 days for the treatment of skin infections in cats (including wounds and abscesses). The clinical status of animals should be re-evaluated after 7 days and the treatment prolonged for a further 7 days if necessary.

Administration is made easier by the palatable nature of the tablet.

Contra-indications, warnings, etc

Do not use in cases of hypersensitivity to penicillins or other substances of the β-lactam group or to any of the excipients.

Do not administer to gerbils, guinea pigs, hamsters, rabbits and chinchillas.

Do not administer to horses and ruminating animals.

Do not use in animals with serious dysfunction of the kidneys accompanied by anuria or oliguaria.

Do not use in cases of known resistance to the combination of amoxicillin and clavulanic acid.

Special precautions for use in animals

In animals with impaired liver and kidney function, the use of the product should be subject to a risk/benefit evaluation by the veterinary surgeon and the posology evaluated carefully.

Caution is advised in the use in small herbivores. Do not administer to those listed above under Contraindications.

Use of the product should be based on susceptibility testing.

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

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin/clavulanic acid and may decrease the effectiveness of treatment with other β-lactam antibiotics, due to the potential for cross resistance.

Narrow spectrum antibacterial therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Do not use in cases of bacteria sensitive to narrow spectrum penicillins or to amoxicillin as a single substance.

The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Adverse reactions (frequency and seriousness)

Vomiting and diarrhoea may be observed very rarely. Treatment may be continued depending on the severity of the undesirable effect observed and a benefit/risk evaluation by the veterinary surgeon.

Hypersensitivity reactions (allergic skin reactions, anaphylaxis) may be observed very rarely. 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).

Use during pregnancy and lactation

The safety of the product has not been established during pregnancy and lactation. Laboratory studies in rats have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

The bactericidal activity of amoxicillin may be reduced by the simultaneous use of bacteriostatic substances such as macrolides, tetracyclines, sulfonamides and chloramphenicol. The potential for allergic cross-reactivity with other pencillins should be considered. Penicillins may increase the effect of aminoglycosides.

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

At three times the recommended dose for a period of 28 days, a decrease in cholesterol values and episodes of vomiting were observed in cats and diarrhoea was observed in dogs. In the event of an overdose, symptomatic treatment is advised.

User warnings

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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this product with great care to avoid exposure, taking all recommended precautions.

3. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Wash hands after handling the tablets

Accidental ingestion of the product by a child may be harmful. To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.

In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.

Pharmaceutical precautions

Do not store above 25°C. Store in the original package.

Any unused half-tablets should be discarded immediately or returned to the open blisters and use within 16 hours.

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

Legal category

Legal category:POM-V

Packaging quantities

Clavaseptin 50 mg Palatable Tablets: 10 and 50 blisters of 10 tablets

Clavaseptin 62.5 mg Palatable Tablets: 10 and 25 blisters of 50 tablets

Clavaseptin 250 mg Palatable Tablets: 10 and 25 blisters of 10 tablets

Clavaseptin 500 mg Palatable Tablets: 10 blisters of 10 tablets

Clavaseptin 750 mg Palatable Tablets: 10 blisters of 10 tablets.

Further information

Amoxicillin is an aminobenzylpenicillin from the β-lactam penicillin family which prevents the bacterial cell wall formation by interfering with the final step of peptidoglycan synthesis.

Clavulanic acid is an irreversible inhibitor of intracellular and extracellular β-lactamases which protects amoxicillin from inactivation by many β-lactamases.

Amoxicillin/clavulanate has a wide range of activity which includes β-lactamase producing strains of both Gram-positive and Gram-negative aerobes, facultative anaerobes and obligate anaerobes.

Resistance to β-lactam antibiotics is mainly mediated by β-lactamases which hydrolyze antibiotics such as amoxicillin.

After oral administration at the recommended dose in dogs and cats, the absorption of amoxicillin and clavulanic acid is fast. In dogs, the maximum plasma concentration of amoxicillin of 8.5 µg/ml is reached in 1.4 h and the maximum plasma concentration of clavulanic acid of 0.9 µg/ml is reached in 0.9h.

In cats, the maximum plasma concentration of amoxicillin of 6.6 µg/ml is reached in 1.8 h and the maximum plasma concentration of clavulanic acid of 3.7 µg/ml is reached in 0.75h. Elimination is also fast.

Half-life is 1 hour in dogs and 1-2 hours in cats for both substances.

After repeated oral administration of the recommended dose in dogs and cats, there is no accumulation of amoxicillin or clavulanic acid and the steady state is reached rapidly after first administration.

Refer to individual SPCs for further information.

Marketing Authorisation Number

Clavaseptin 50 mg Palatable Tablets: UK: Vm 08007/4113

Clavaseptin 62.5 mg Palatable Tablets: UK: Vm 08007/4135

Clavaseptin 250 mg Palatable Tablets: UK: Vm 08007/4114

Clavaseptin 500 mg Palatable Tablets: UK: Vm 08007/4115

Clavaseptin 750 mg Palatable Tablets: UK: Vm 08007/4176

Significant changes

GTIN

GTIN description: Clavaseptin 50 mg 10 x 10

GTIN:03605874367821

GTIN description: Clavaseptin 50 mg 50 x 10

GTIN:03605874367838

GTIN description: Clavaseptin 62.5 mg 10 x 10

GTIN:03605874367845

GTIN description: Clavaseptin 62.5 mg 50 x 10

GTIN:03605874367852

GTIN description: Clavaseptin 250 mg 10 x 10

GTIN:03605874367791

GTIN description: Clavaseptin 250 mg 25 x 10

GTIN:03605874367807

GTIN description: Clavaseptin 500 mg 10 x 10

GTIN:03605874367814

GTIN description: Clavaseptin 750 mg 10 x 10

GTIN:03605874619555