clavubactin® 50/12.5mg

Tablets for Cats and Dogs

Amoxicillin and Potassium clavulanate

Statement of the active substances and other ingredients

Active substances per tablet:

Amoxicillin (as amoxicillin trihydrate)	50mg
Clavulanic acid (as potassium clavulanate)	12.5mg

Other ingredients

Quinoline yellow lacquer (E104)	0.06mg
Titanium dioxide (E171)	0.10mg

Yellowish-white to light yellow round tablet with a cross-shaped break mark on one side.
The tablets can be divided into 4 equal parts.

Indications

Treatment of infections in cats and dogs caused by bacteria sensitive to amoxicillin in combination with clavulanic acid, particularly:

- Skin infections (including superficial and deep pyodermas) associated with Staphylococci (including beta-lactamase producing strains) and Streptococci.
- Urinary tract infections associated with Staphylococci (including beta-lactamase producing strains), Streptococci, *Escherichia coli* (including beta-lactamase producing strains), *Fusobacterium necrophorum* and *Proteus* spp.
- Respiratory tract infections associated with Staphylococci (including beta-lactamase producing strains), Streptococci and Pasteurellae.
- Gastrointestinal tract infections associated with *Escherichia coli* (including beta-lactamase producing strains) and *Proteus* spp.
- Infections of the oral cavity (mucous membrane) associated with Clostridia, Corynebacteria, Staphylococci (including beta-lactamase producing strains), Streptococci, *Bacteroides* spp (including beta-lactamase producing strains), *Fusobacterium necrophorum* and Pasteurellae.

Contraindications

Do not use in animals with known hypersensitivity to penicillin or other substances of the beta-lactam group or any of the excipients.
Do not use in serious dysfunction of the kidneys accompanied by anuria and oliguria.
Do not use in rabbits, guinea pigs, hamsters, chinchillas and gerbils.
Do not use in case of known resistance to the combination.

Adverse reactions

Mild gastrointestinal symptoms (diarrhoea, nausea and vomiting) may occur after administration of the product.
Allergic reactions (skin reactions, anaphylaxia) may occasionally occur. In these cases, administration should be discontinued and a symptomatic treatment given.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Target species

Dogs and cats.

Dosage for each species, route(s) and method of administration

Posology

For oral administration only.

Dosage

The recommended dose is 12.5mg of combined active substance (=10mg amoxicillin and 2.5mg clavulanic acid) per kg bodyweight, twice daily.
The following table is intended as a guide to dispensing the product at the standard dose rate of 12.5mg of combined actives per kg bodyweight twice daily.

Number of tablets twice daily

Bodyweight (kg)	amoxicillin 50mg/ clavulanic acid 12.5mg	amoxicillin 250mg/ clavulanic acid 62.5mg	amoxicillin 500mg/ clavulanic acid 125mg
1 – 1.25	▱		
1.25 – 2.5	◗		
2.5 – 3.75	◗▱		
3.75 – 5	◗◗		
5 – 6.25	◗◗▱	▱	
6.25 - 12.5		◗	▱
12.5 - 18.75		◗▱	
18.75 - 25		◗◗	◗
25 - 31.25		◗◗▱	
31.25 - 37.5		◗◗◗	
37.5 - 50			◗◗
50 – 62.5			◗◗▱
62.5 - 75			◗◗◗

In refractory cases of skin infections, a double dose is recommended (25mg per kg bodyweight, twice daily).

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.

Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

Special storage precautions

Do not store above 25˚C.
Store in the original container.
Keep out of the sight and reach of children.
Quarter tablets should be returned to the opened strip and stored in a refrigerator.
Shelf-life of tablet quarters: 12 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

Special warnings

Special precautions for use in animals

Official, national and regional antimicrobial policies should be taken into account when the product is used.
Do not use in case of bacteria sensitive to narrow spectrum penicillins or to amoxicillin as a 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 due to the potential for cross-resistance.
In animals with hepatic and renal failure, the dosing regimen should be carefully evaluated.
Caution is advised in the use in small herbivores other than those in the Contraindications section.

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 and lactation

Laboratory studies in rats and mice have not produced any evidence of teratogenic or fetotoxic effects. No studies have been conducted in pregnant or lactating dogs and cats. 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 effects of penicillins.
The potential for allergic cross-reactivity with other penicillins should be considered.
Penicillins may increase the effect of aminoglycosides.

Overdose

Mild gastrointestinal signs (diarrhoea, nausea and vomiting) may occur more frequently after overdose of the product.

Special precautions for the disposal of unused product or waste material, if any

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Date on which the package leaflet was last approved: September 2015

Other information

Pack sizes

Carton containing 5 aluminium/aluminium blister strips each strip with 2 tablets corresponding to 10 tablets per carton.
Carton containing 5 aluminium/aluminium blister strips each strip with 4 tablets corresponding to 20 tablets per carton.
Carton containing 25 aluminium/aluminium blister strips each strip with 4 tablets corresponding to 100 tablets per carton.
Carton containing 1 aluminium/aluminium blister strip with 10 tablets corresponding to 10 tablets per carton.
Carton containing 10 aluminium/aluminium blister strips each strip with 10 tablets corresponding to 100 tablets per carton.
Carton containing 25 aluminium/aluminium blister strips each strip with 10 tablets corresponding to 250 tablets per carton.
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.

Marketing Authorisation Holder:
Le Vet Beheer B.V., Wilgenweg 7,
3421 TV Oudewater, The Netherlands

Manufacturer responsible for batch release:
Lelypharma B.V., Zuiveringweg 42, 8243 PZ Lelystad, The Netherlands

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For animal treatment only.

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