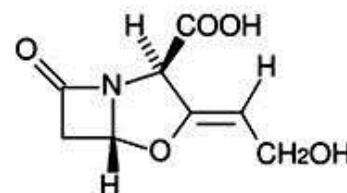




AMOXIPET PLUS 50

Broad-spectrum beta-lactam antibiotic



REGISTRATION NUMBER Q- 7972-042

FORMULA:

Amoxicillin trihydrate..... 50 mg.
Clavulanic acid..... 12.4 mg.
Excipient c.b.p.....1 tablet.



Presentation box with 30 tablets

DESCRIPTION:

Broad-spectrum β -lactam antibiotic with bactericidal effect and inhibitory action of β -lactamases. It can be used in puppies, adults and in lactating females.

DIRECTIONS:

Treatment of bacterial infections caused by agents sensitive to Amoxicillin. Including β -lactamase producing strains. Its use is recommended in pyodermas, abscesses, wounds, cellulitis, otitis media, urogenital, respiratory infections before and after, gingivitis and alveolar abscess and osteomyelitis.

PHARMACOLOGY

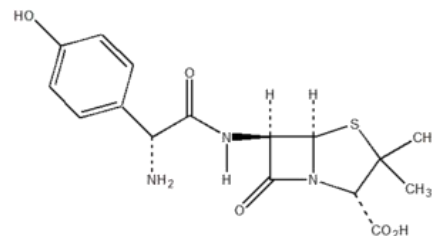
Amoxicillin is a semi-synthetic penicillin with a wide spectrum of action, which acts against both Gram positive and Gram negative, aerobic and anaerobic bacteria, such as: *E. coli*, anaerobic as *Clostridium* sp some strains of *Proteus mirabilis*, *Haemophilus influenzae*, *Haemophilus* sp and the genera *Salmonella* and *Shigella*.

Clavulanic acid, an antibiotic produced by cultures of *Streptomyces clavuligerus*, is a beta-lactamase inhibitor. It has a weak antibacterial activity, but nevertheless, it is a powerful inhibitor of beta-lactamases generated by Gram-positive and enterobacteriaceae bacteria (Gram-negative bacteria in general) such as: *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Haemophilus* sp. And *Bacteroides fragilis*, *Salmonella* and *Shigella* and *E. coli*. The combination of amoxicillin with potassium clavulanate (clavulanic acid) produces a very potent combination even against penicillin bacterial strains or resistant beta-lactamases.

PHYSICOCHEMICAL CHARACTERISTICS:

Amoxicillin is an odorless, white, crystalline water-soluble powder. Amoxicillin structurally has a hydroxyl group in the characteristic phenyl ring Amoxicillin is also known as p-hydroxyampicillin, or BRL 2333. It should be stored at room temperature (15-30°C).

Chemically, amoxicillin is: 2S,5R,6R-6-[(R) - (-) -2-amino-2-(4-hydroxyphenyl) acetamido]-3, 3-dimethyl-7-oxo- 4-thia-1-azabicyclo [3.2.0] heptane-2-carboxylic.



Clavulanic acid is a white crystalline powder that has a pKa of 2.7 (like acid), is very soluble in water and slightly in alcohol at room temperature. Although as potassium salt, the potency is expressed in terms of clavulanic acid. Synonyms are: clavulanic acid and clavulanic potassium



It has a molecular formula of: $C_8H_8K N O_5$ and a molecular weight of 237.25. Chemically it is (Z)-(2R,5R)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0] - heptane-2-carboxylate.

MECHANISM OF ACTION:

Amoxicillin has a bactericidal effect because it interferes by inhibiting the synthesis of peptidoglycans from the bacterial wall promoting the rupture of the same causing the death of the bacteria.

With the discovery of β -lactamases, the main mechanism of antimicrobial resistance against lactam β was found, since they hydrolyze the amide bond of the β -lactam ring, producing acid derivatives lacking antibacterial activity.

Clavulanic acid alone has very low antimicrobial activity, despite sharing the β -lactam ring that is characteristic of β -lactam antibiotics. The inhibitory capacity of clavulanic acid is due to the structural similarity it maintains with penicillins and cephalosporins. The inhibition action it exerts is progressive and irreversible and has a considerably greater affinity for beta-lactamases than that of beta-lactam antibiotics, which is an essential property in a good inactivator.

Clavulanic acid acts, entering through the bacterial wall and in the case of Gram-negative bacteria, it finds beta-lactamases in the periplasmic space, and joins the catalytic center of these, effecting a chemical reaction, which originates an inactive compound: Enzyme-clavulanic acid, resulting in the destruction of beta-lactamase and clavulanic acid, so it is also called a suicide inhibitor.

PHARMACOKINETICS:

The combination present in Amoxipet Plus administered orally, is well absorbed by the gastrointestinal tract (75 to 90%), presenting great stability in gastric juices, so it can be administered regardless of whether they have consumed food, although the best effects are observed when administered during feeding.

Amoxicillin reaches good therapeutic levels in kidneys, liver, heart, skin, lungs, intestines, bile, bones, prostate, peritoneal, pleural and synovial fluid, including levels are adequate in cerebrospinal fluid. It binding to a greater or lesser degree to plasma proteins and also crosses the placental barrier. It is rapidly excreted largely unchanged by the kidneys in the urine through glomerular filtration and tubular secretion. The activity of amoxicillin in vitro is similar to that of ampicillin but is better absorbed when administered orally, even has greater stability in acidic medium.

The maximum blood concentration is two and a half times higher than that achieved with a similar dose of ampicillin. The food does not decrease its absorption.

Potassium clavulanate is relatively stable in the presence of gastric acid and is easily absorbed. In dogs, peak levels occur about 1 hour after administration. It has a volume of distribution of 0.32 l / kg in dogs and is distributed (with amoxicillin) in the lungs, pleural fluid and peritoneal fluid, low concentrations of this combination have been found in salivary secretion.

Clavulanic acid is 13-20% binding to plasma proteins, crosses the placental barrier but does not cause teratogenic problems. 52% of the dose is excreted in the urine as an unchanged drug (by glomerular filtration) and metabolites, 25-27% is excreted in the feces, and 16-33% by respiratory route.

The beta phase of the elimination half-life in patients with normal renal function is approximately one hour. The half-life is prolonged in patients with kidney damage (e.g. eight to 16 hours in anuric patients) and an adjustment in dose or interval of administration is necessary.

ROUTE OF ADMINISTRATION: Oral.

DOSE:

Canines: Administer 10 to 20 mg/ kg of Amoxicillin every 8-12 hours from 5 to 30 days at the discretion of the Veterinarian. Equivalent to 1 tablet per 2.5 to 5 kg of weight.

Felines: 50 mg total dose of amoxicillin every 12 hours. Equivalent to a tablet

In Dogs and Cats: When the infection is caused by Gram negative bacteria it is recommended to use the high dose 20 mg / kg one tablet per 2.5 kg of weight.

In deep pyodermas require treatment for 21 days. The maximum duration of treatment should not exceed 30 days.

In the treatment of urinary tract infections may require 10 to 14 days.

DRUG INTERACTIONS:

It has synergistic with other penicillins. It improves its absorption if administered on an empty stomach, but it is irritating so it is recommended to administer half an hour before eating or an hour after. Neomycin blocks its absorption. Tetracyclines, chloramphenicol and erythromycin are antagonists.

ADVERSE EFFECTS

Like all penicillins it can cause anaphylaxis or allergic reactions, which can be treated with epinephrine and/or steroids. Discontinue immediately in case of adverse reactions. It rarely causes pharyngitis and dysphagia, so it is recommended to administer with food.

The use of this product is contraindicated in patients with a history of allergic reaction to penicillins or cephalosporins.

WARNINGS:

Discontinue immediately in case of adverse reactions. Keep in a dry, cool place. Protect yourself from the light. Keep out of reach of children. Product for exclusive use in veterinary medicine.

Consult the Veterinary Zootechnician

Exclusive literature for veterinarians.

Its sale requires a prescription.

Content Managers: Technical Department

Bibliography

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