



Dejando huella en la  
Industria de la Salud Animal

## AMOXIPET PLUS suspension

*Broad-spectrum beta-lactam antibiotic*

**REGISTRATION NUMBER Q- 7972-106**

**FORMULA:**

Amoxicillin trihydrate..... 50 mg.

Clavulanic acid..... 12.5 mg.

Vehicle c.b.p.....1 ml.

**PRESENTATION:**

AMOXIPET PLUS suspension: 15 ml.



**DESCRIPTION:**

Broad-spectrum  $\beta$ -lactam antibiotic with bactericidal effect and inhibitory action of  $\beta$ -lactamases. It can be used in puppies, adults and pregnant females.

**DIRECTIONS:**

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

**FAEMACOLOGY**

Indicated for acute and chronic infections of the respiratory tract, as well as for genitourinary infections, enteric infections, skin such as pyodermas, abscesses, wounds, cellulitis, otitis media and soft tissue produced by Gram positive, Gram negative bacteria; aerobics and anaerobes, as well as beta-lactamase-producing bacteria and some resistant to penicillin, ampicillin and amoxicillin alone that affect dogs and cats.

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.

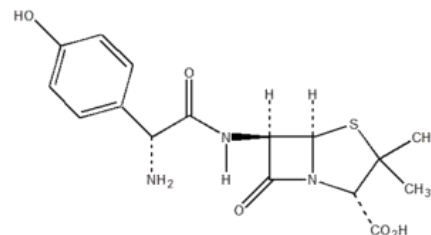


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### PHYSICOCHEMICAL CHARACTERISTICS:

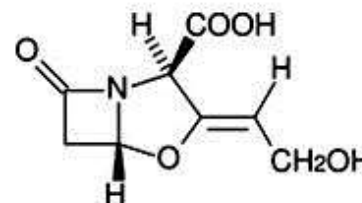
Amoxicillin is an odorless, white, crystalline water-soluble powder. Amoxicillin structurally differs from ampicillin only by having a hydroxyl group in the phenyl ring. Amoxicillin is also known as p-hydroxyampicillin, or BRL 2333. It should be stored at room temperature (15-30°C).

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<sub>8</sub>H<sub>8</sub>N<sub>2</sub>O<sub>5</sub> 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  $\beta$ -lactamases, the main mechanism of antimicrobial resistance against lactam  $\beta$  was found, since they hydrolyze the amide bond of the  $\beta$ -lactam ring, producing acid derivatives lacking antibacterial activity. Clavulanic acid alone has very low antimicrobial activity, despite sharing the  $\beta$ -lactam ring that is characteristic of  $\beta$ -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, introducing itself 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 suspension 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.



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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.

#### 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 ml per 2.5 to 5 kg of weight.

**Felines:** 50 mg of Amoxicillin every 12 hours. Equivalent 1 ml per cat.

#### In Dogs:

- When the infection is caused by Gram-negative bacteria it is recommended to use the high dose 1 ml per 2.5 kg of weight.
- In deep pyodermas require treatment for 21 days. The maximum duration of treatment should not exceed 30 days. Treatment of UTIs may require 10 to 14 days.

#### En Gatos:

- Cuando la infección es provocada por bacterias Gram negativas se recomienda usar la dosis alta 1 ml por cada 2.5 kg de peso.
- Se puede modificar la dosis y tiempo de tratamiento a criterio del Médico veterinario

**ROUTE OF ADMINISTRATION:** Oral.

#### MODE OF PREPARATION:

Add boiled, cold water to the mark. Shake perfectly before use.

Shake well before use once the mixture is made, the product is stored for 7 days at room temperature or 14 days in refrigeration

#### 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:

Amoxicillin rarely produces rare and transient side effects. It is recommended to give along with food. Do not use patients allergic to penicillins. In case of allergic reactions discontinue use immediately. Keep in a dry place, cool at no more than 30°C and protected from direct sunlight. **Do not leave it within reach of children, pets and disabled people. 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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GLP

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