

CLAMENTIN Film Coated Tablet 625mg



Ingredient(s):

Each film-coated tablet contains:

Amoxicillin (as Trihydrate) 500mg
Clavulanic Acid (as Potassium Salt) 125mg

Pharmacodynamics:

Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it can act on the pathogen. The clavulanate in Clamentin anticipates this defense mechanism by blocking the β -lactamase enzymes, thus rendering the organisms sensitive to amoxicillin's rapid bactericidal effect at concentrations readily attainable in the body.

Clamentin is bactericidal to a wide range of organisms including:

Gram-positive:

Aerobes: **Enterococcus faecalis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus viridans*, **Staphylococcus aureus*, *Coagulase-negative staphylococci (including *Staphylococcus epidermidis*), *Corynebacterium* sp, **Bacillus anthracis*, *Listeria monocytogenes*, *Enterococcus faecium*, *Streptococcus agalactiae*, *Streptococcus* sp.

Anaerobes: *Clostridium*, *Peptococcus* spp, *Peptostreptococcus*.

Gram-negative:

Aerobes: **Haemophilus influenzae*, **Escherichia coli*, **Proteus mirabilis*, **Proteus vulgaris*, **Klebsiella* sp, **Moraxella catarrhalis* (*Branhamella catharralis*), **Salmonella* sp, **Shigella* sp, *Bordetella pertussis*, *Brucella* sp, **Neisseria gonorrhoeae*, **Neisseria meningitidis*, *Vibrio cholerae*, **Yersinia enterocolitica*, *Pasteurella multocida*, *Gardnerella vaginalis*, *Helicobacter pylori*, *Legionella* sp.

Anaerobes: **Bacteroides* sp (including *Bacteroides fragilis*), **Fusobacterium* sp.

*Including β -lactamase producing strains resistant to ampicillin and amoxicillin.

Pharmakinetics:

Amoxicillin and clavulanate potassium are well absorbed from the gastrointestinal tract after oral administration. Dosing in the fasted or fed state has minimal effect on the pharmacokinetics of amoxicillin. While Clamentin can be given without regard to meals, absorption of clavulanic acid when taken with food is greater relative to the fasted state.

Amoxicillin serum concentrations achieved with Clamentin are similar to those produced by the oral administration of equivalent doses of amoxicillin alone. The half-life of amoxicillin after oral dministration is 1.3 hours and that of clavulanic acid is 1.0 hour.

Concurrent administration of probenecid delays amoxicillin excretion but does not delay renal excretion of clavulanic acid.

Clavulanic acid has been found to be approximately 25 % bound to human serum and amoxicillin approximately 18 % bound.

Amoxicillin diffuses readily into most body tissues and fluids with the exception of the brain and spinal fluid. The results of experiments involving the administration of clavulanic acid to animals suggest that this compound, like amoxicillin, is well distributed in body tissues.

Indication(s):

Clamentin are indicated for short-term treatment of bacterial infections at the following sites:

- Upper respiratory tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media.
- Lower respiratory tract infections e.g. acute and chronic bronchitis, lobar and bronchopneumonia.
- Genito-urinary tract infection e.g. cystitis, urethritis, pyelonephritis.
- Skin and soft tissue infections e.g. boils, abscesses, cellulites, wound infections.
- Bone and joint infections e.g. osteomyelitis.
- Dental infections e.g. dentoalveolar abscess.
- Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis.

Clamentin is bactericidal to a wide range of organisms including:

Gram positive

Aerobes: *Enterococcus faecalis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus viridans*, **Staphylococcus aureus*, *Coagulase negative staphylococci (including *Staphylococcus epidermidis*), *Corynebacterium species*, *Bacillus anthracis*, *Listeria monocytogenes*.

Anaerobes: *Clostridium species*, *Peptococcus species*, *Peptostreptococcus*.

Gram Negative

Aerobes: **Haemophilus influenzae*, **Escherichia coli*, **Proteus mirabilis*, **Proteus vulgaris*, **Klebsiella* species, **Moraxella catarrhalis*, **Salmonella* species, **Shigella* species, *Bordetella pertussis*, *Brucella* species, **Neisseria gonorrhoeae*, *Neisseria meningitidis*, *Vibrio cholerae*, *Pasteurella multocida*.

Anaerobes: **Bacteroides* spp. Including **B. fragilis**.

*including beta-lactamase producing strains resistant to ampicillin and amoxicillin.

Dosage and Administration:

Usual dosages for the treatment of infection

Adults and children over 12 years

Mild-Moderate infections : One Clamentin Film Coated Tablet 625 mg two times a day.

Therapy can be started parenterally and continued with an oral preparation.

Dosage in dental infections (e.g. dentoalveolar abscess)

Adult and children over 12 years: One Clamentin Film Coated Tablet 625 mg two times a day for five days.

Clamentin Film Coated Tablet 625 mg is not recommended in children of 12 years and under.

Dosage in renal impairment

Adult:

Mild impairment (Creatinine clearance >30 mL/min) : No change in dosage.

Moderate impairment (Creatinine clearance 10-30 mL/min) : One Clamentin 625 mg a day.

(Depending on severity of infection)

Severe impairment (Creatinine clearance <10 mL/min) : Not more than one Clamentin 625 mg every 24 hours.(Depending on severity of infection)

Dosage in hepatic impairment

Dose with caution; monitor hepatic at regular intervals.

Route of Administration:

Oral

Contraindication(s):

1. Penicillin hypersensitivity.
2. Attention should be paid to possible cross-sensitivity with other β -lactam antibiotics, e.g. cephalosporins.
3. A previous history of Clamentin or penicillin-associated jaundice/hepatic dysfunction.

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Precaution(s) / Warning(s):

1. Clamentin should be used with caution in patients with evidence of hepatic dysfunction.
2. Cholestatic jaundice, which may be severe, but is usually reversible, has been reported rarely. Signs and symptoms may not become apparent for up to six weeks after treatment has ceased.
3. In patients with moderate or severe renal impairment, dosage should be adjusted.
4. Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy.
5. Erythematous rashes have been associated with glandular fever in patients following the use of amoxicillin. Clamentin should be avoided if glandular fever is suspected.
6. During the administration of high doses, adequate fluid intake and urinary output should be maintained to minimize the possibility of crystalluria.
7. Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.

Interaction with Other Medicaments

Prolongation of bleeding time and prothrombin time may be possible. Clamentin should be used with care in patients on anti-coagulation therapy.

In common with other broad-spectrum antibiotics, Clamentin may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

Concomitant use of Probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use with Clamentin may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid.

Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. There are no data on the concomitant use of Clamentin and allopurinol.

Pregnancy and Lactation

1. Use in pregnancy
Reproduction studies in animals (mice and rats) with orally and parenterally administered. Clamentin have shown no teratogenic effects. As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician.
2. Use in lactation
Clamentin may be administered during the period of lactation. With the exception of the risk of sensitization associated with the excretion of trace quantities in breast milk, there are no detrimental effects for the infant.

Side Effect(s) / Adverse Reaction(s):

Side effects, as with amoxicillin, are uncommon and mainly of a mild and transitory nature.

Gastrointestinal reactions

Effects include diarrhoe, indigestion, nausea and vomiting. Candidiasis, antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) have been reported rarely. Nausea although uncommon, is more often associated with higher oral dosages. If gastrointestinal side effects occur with oral therapy they may be reduced by taking Clamentin at the start of meals. As with other antibiotics the incidence of gastrointestinal side effects may be raised in children under 2 years. In clinical trials, however, only 4 % of children under 2 years were withdrawn from treatment.

Hepatic effects

A moderate rise in AST and/or ALT has been noted in patients with semi-synthetic penicillins but the significance of these findings is unknown.

Hepatitis and cholestatic jaundice have been reported rarely with Clamentin. They may however be severe and continue for several months. They are reported as occurring predominantly in adult or elderly patients and slightly more frequently in males. Signs and symptoms may occur during treatment but are more frequently reported after cessation of therapy with a delay of up to six weeks.

The hepatic events are usually reversible. However, in extremely rare circumstances, deaths have been reported. Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment.

Hypersensitivity reactions

Urticarial and erythematous rashes sometimes occur. Rarely erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis and exfoliative dermatitis have been reported. Treatment should be discontinued if one of these types of rash appears.

In common with other β -lactam antibiotics, angioedema, oedema, anaphylaxis, serum sickness-like syndrome and hypersensitivity vasculitis have been reported.

Interstitial nephritis can occur rarely.

Haematological effects

As with other β -lactams reversible leucopenia (including neutropenia or agranulocytosis) reversible thrombocytopenia and haemolytic anaemia have been reported rarely.

CNS effects

CNS effects have been seen very rarely. These include reversible hyperactivity, dizziness, headache and convulsions. Convulsions may occur with impaired renal function or in those receiving high doses.

Skin and subcutaneous tissue disorders:

Frequency 'very rare': Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

Overdosage: Cases of overdosage with Clamentin are unlikely to occur; if encountered gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. They may be treated symptomatically with attention to the water electrolyte balance.

Clamentin may be removed from the circulation by haemodialysis.

Symptoms and Treatment of Overdose

Cases of overdosage with amoxicillin-clavulanic acid are usually asymptomatic. If encountered, gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. They may be treated symptomatically with attention to the water electrolyte balance. Clamentin can be removed from the circulation by haemodialysis.

Shelf-Life:

2 years from the date of manufacture.

Storage Condition(s):

Store at room temperature below 30°C. Protect from light and moisture.

Product Description and Packing(s):

A white to off-white film coated tablet in a shape of " YSP 3 " " "

Blister packing of 10's x 10.



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Acknowledgement



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