

Product Detail

Anqi

Mechanism of action

Anqi is an oral antibacterial combination consisting of the semisynthetic antibiotic amoxicillin and the β -lactamase inhibitor, clavulanate potassium (the potassium salt of clavulanic acid). Amoxicillin is an analog of ampicillin.

Clavulanic acid is a β -lactam structurally related to the penicillins and possesses the ability to inactivate a wide variety of β -lactamases by blocking the active sites of these enzymes. Combination of amoxicillin and clavulanate potassium may prevent amoxicillin from hydrolyzed by β -lactamase.

Anqi has similar but broader antimicrobial spectrum with that of amoxicillin.

It exhibits good antimicrobial activity against *Staphylococcus aureus* (β -lactamase producing), *Staphylococcus epidermidis*, *Staphylococcus saprophyticus*, enterococci, *Enterobacter* species (β -lactamase and non- β -lactamase-producing), *Haemophilus influenzae*, *Moraxella catarrhalis*, *Bacteroides* species (including *Bacteroides fragilis*).

Anqi is not active against MRSA, *P. aeruginosa* and *Enterobacter* species (plasmid-mediated β -lactamases producing).

Pharmacokinetics

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.

Following 375mg anqi was administered oral, (amoxicillin 250mg, clavulanate potassium 125mg), peak plasma concentration of amoxicillin (5.6mg/L) is achieved at 1.5 hr (C_{max}), ($t_{1/2\beta}$) is 1hr. 50%~78% of amoxicillin is excreted in urine within 8 hr. peak plasma concentration of clavulanate potassium is (3.4mg/L) is achieved at 1 hr. Protein binding is 22%~30%. $t_{1/2\beta}$ is 0.76~1.4 hr, 46% of clavulanate potassium is excreted via urine within 8 hrs. Bioavailability is 97% and 75% respectively.

Clinical application

This product can be used for the following infection due to susceptible microorganism: respiratory infection, urinary tract infection and skin and soft tissue infection.

Indication

This product indicated for:

lower respiratory tract infections, otitis media, sinusitis due to the influenzae producing haemophilus and *Moraxella catarrhalis* bacteria; the respiratory tract, urinary tract and skin and soft tissue infections caused by *Staphylococcus aureus* and *Enterobacteriaceae* producing bacteria such as *E. coli*, *Klebsiella*; mild to moderate infections due to the Enterococci infection

The product is also indicated for above infections caused by non-enzyme-producing bacteria.

Adverse effects

- 1、gastrointestinal symptoms: diarrhea, nausea and vomiting.
- 2、Skin rash, especially due to infectious mononucleosis.

- 3、rare case of allergy shock, drug fever and asthma.
- 4、rare case of moderate rise of transaminase, eosinophilia, leukopenia and super-infection due to *Candida*.

Precaution

1. Caution should be exercised to patients with history of allergy to cephalosporin, asthma, exzema, hay fever, urticaria and other hypersensitivity, patients with severely impaired hepatic function.
- 2、Cefaclor has cross allergic response with PCs or cephamycin, so patient who is allergic to patient who is allergic to PCs, penicillin derivate, bellacillin, and other cephalomycin should take it with caution.
- 3、Cefaclor has cross allergic response with ampicillin, so patient who is allergic to patient who is allergic to PCs, penicillin derivate should take it with caution.
- 4、The patients with impaired renal function may require dose adjustment based on serum creatine clearance.

Hemodialysis may have impact the serum concentration of amoxicillin. One additional dose of this product is required upon completion of hemodialysis.

- 5、For suspected patient of gonorrhea, dark vision fildes test is required before taking this product.
- 6、Patients with severely impaired hepatic function should take this product with caution. Hepatic, renal and hematologic system function test should e conducted st regular basis.
- 7、 **Laboratory Test Interactions:** (1) High urine concentrations of amoxicillin may result in false-positive reactions when testing for the presence of glucose in urine using CLINITEST®, Benedict's Solution, or Fehling's Solution. (2) May cause elevation of test value of AST/ALT.

Pregnant and Nursing Mothers : (1) Ampicillin-class antibiotics can penetrate through placenta. Therefore, taking Anqi is contraindicated by pregnant women.

- 2、Small amount of Amoxicillin may be excreted into mother's milk. Amoxicillin used by nursing mother may lead to sensitization of infants. Therefore, caution should be exercised to nursing women when taking this product.

Dosage and administration

This product should be orally.

For ault with medium to severe infection: 625mg once, given 3 times per day. Once cycle lasts for 7~10 days.

For pediatric use:

New born or Infants within 3 months: Amoxicillin 15mg/kg each time, twice a day.

Children with body weight ≤40kg: a) General Infection: Amoxicillin 15mg/kg each time, twice a day; or Amocixillin 20mg/kg, 3 times a day. One cycle lasts 7~10 days. b) Other infectious situation: half dose of above schedule.

Children with body weight above 40kg could use adult dosage.

For Patients with insufficient renal function: patients with CrCl >30ml/min need not to reduce dose; patients with CrCl between 10 to 30ml/min use 250~500mg(Amoxicillin) oral dosage every 12 hrs; patients with CrCl <10ml/min take the product by 250~500mg (Amoxicillin) daily dose.

For patients with hemodialysis: oral administration of 250~500mg (Amoxicillin) every 24 hrs referring to individual situation; additional doses are required during and after hemodialysis.

Properties and appearance

The Granules is white to yellowish and sweet.

Specification

This product is is an antibacterial combination consisting of the amoxicillin and clavulanate potassium.

Each Granules contains 0.125g of amocixillin and 31.25 mg of clavulanate potassium.

Package

Double composite membrane packaging, 6 bags / box

Price

20 RMB/box