

AMOXICILLIN SODIUM & CLAVULANATE POTASSIUM FOR INJECTION

COMPOSITION

Each vial of 600 mg contains Amoxicillin (as sodium salt) to 500 mg and 100mg clavulanic acid (as potassium salt).

Each vial of 1.2 g contains Amoxicillin (as sodium salt) to 1g and 200mg clavulanic acid (as potassium salt).

INDICATIONS:

The formulation of Amoxicillin, a bactericidal β - lactam penicillin antibiotic, and Clavulanic Acid, an irreversible β - lactamase inhibitor, is a bactericidal antibiotic, with a broad spectrum of bactericidal activity against Gram-Positive and Gram-negative aerobic and anaerobic bacteria. The presence of Clavulanic Acid in the formulation extends the spectrum of activity of amoxicillin to include many β - lactamase-producing bacteria normally resistant to Amoxicillin and β - lactam antibiotics.

The combination of SKYCLAV is indicated for the treatment of :

- Upper respiratory tract infections (Sinusitis, tonsillitis, otitis media)
- Lower respiratory tract infections(pneumonia, empyema, lung abscess, bronchitis)
- Genito-urinary tract and abdominal infections (cystitis, pyelonephritis, urethritis, pelvic infection, gonorrhoea and intra-abdominal sepsis)
- Soft tissue and dermal infections (wound infections, animal bites and severe dental abscess with spreading cellulitis)

The combination of SKYCLAV can be also be used for prophylaxis against infections associated with major surgical procedures in adult, such as those involving the gastrointestinal tract, pelvic cavity, head and neck, and biliary tract.

The injection should be reversed for severe infections.

RECONSTITUTION

- For IV injection:
Dissolve **SKYCLAV** 600mg in 10 ml water for injections or sodium chloride 0.9%.
Dissolve **SKYCLAV** 1.2g in 20 ml water for injections or sodium chloride 0.9%.
Give by slow intravenous injection over a period of three to four minutes and use immediately after reconstitution.
- For IV infusion:
Add the reconstituted **SKYCLAV** 600 mg solution to 50 ml of infusion fluid.
Add the reconstituted **SKYCLAV** 1.2 g solution to 100 ml of infusion fluid.
Infuse over 30 – 40 minutes and infusions containing glucose, dextran or bicarbonate.

DOSAGE

Doses are expressed in terms of **SKYCLAV** content. Duration of therapy should be appropriate to the indication and should not exceed 14 days without review.

Infections:

Adults and Children \geq 40kg: 1.2g every 8 hours

Children < 40 kg

Children aged 3 months and over: 30 mg per kg every 8 hours

Children aged less than 3 months or weighing less than 4 kg: 30 mg per kg every 12 hours by IV infusion only surgical prophylaxis:

Adults: The usual dose is 1.2 g given at the induction of an anaesthesia. Operations where there is a high risk of up to four doses of 1.2 g in a 24-hour period.

Renal Impairment

No dose adjustment is required in patients with creatinine clearance (CrCl) greater than 30 ml/ min.

Adults and Children \geq 40 kg:

CrCl: 10 – 30 ml/min: Initial dose of 1.2 g and then 600mg given twice daily

CrCl < 10 ml/ min: Initial dose of 1.2 g and then 600 mg given every 24 hours

Children < 40 kg

CrCl: 10 – 30 ml/min: 30 mg per kg given every 12 hours.

CrCl < 10 ml/ min: 30 mg per kg given every 24 hours.

PREGNANCY AND BREAST FEEDING

Use should be avoided in pregnancy, especially during first trimester. **SKYCLAV** should be considered appropriate

When the potential benefits outweigh the potential risks associated with treatment. **SKYCLAV** may be given with caution during lactation.

CONTRA-INDICATIONS AND WARNINGS:

SKYCLAV should be used for infections likely, or known, to be caused by Amoxicillin-resistant, β -lactamase-producing strains. Do not use in case of hypersensitivity to penicillins. Cross allergy to other β -lactams such as cephalosporins should be taken into account. Contra-indicated in previous history of **SKYCLAV** or penicillin-associated jaundice or hepatic dysfunction. Use with caution in patients with evidence of hepatic dysfunction. Avoid in infectious mononucleosis, because of the risk of skin rashes; patients with lymphatic leukaemia or possibly HIV infection may also be at increased risk. Erythematous rashes have been associated with glandular fever in patients on a controlled potassium diet.

Amoxicillin has been reported to precipitate in bladder catheters, predominantly after intravenous administration of large doses.

Amoxicillin may reduce the efficacy of oral contraceptives and patients should be warned accordingly. **SKYCLAV** injection should not be mixed with blood products, other proteinaceous fluid such as protein hydrolysates or with intravenous lipid emulsions. Do not mix in the syringe, intravenous fluid container or giving set with an aminoglycoside because loss of activity of the aminoglycoside can occur under these conditions.

SIDE EFFECT

Side-effects are uncommon and mainly of a mild and transitory nature. Gastro-intestinal reactions e.g. nausea, diarrhea, vomiting and mucocutaneous candidiasis have been reported. Genito-urinary effects e.g. vaginal itching, soreness and discharge may occur. Hepatitis and jaundice have been reported rarely with the combination **SKYCLAV**; the Clavulanic Acid component has been implicated. The risk increases with the duration of treatment longer than 14 days. Signs and symptoms may not become apparent for several weeks after treatment has ceased. Rarely erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, interstitial nephritis and exfoliative dermatitis have been reported. As with other β -lactams transient leucopenia (including neutropenia and agranulocytosis), renal function or in those receiving high doses. During the administration of high dose of Amoxicillin, maintain adequate fluid intake and urinary output to reduce the possibility of Amoxicillin crystalluria. Rarely thrombophlebitis at the site of injection.

OVERDOSAGE

Over dosage: Gastrointestinal symptoms, disturbance of the fluid and electrolyte balances, and convulsion (especially in patients with renal impairment) may occur.

Treatment: Symptomatic. **SKYCLAV** can be removed from the circulation by haemodialysis.

DRUG INTERACTION

1. Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions.
2. **SKYCLAV** should be used with care in patients on anti-coagulation therapy e.g. warfarin, as prolongation of bleeding time and prothrombin time have been reported in some patients.
3. **SKYCLAV** may reduce the efficacy of oral contraceptives

STORAGE

Store the powder below 25°C in a dry place, protect from light.

KEEP OUT OF REACH OF CHILDREN

Manufactured for: ESKAY THERAPEUTICS LTD., P. O. BOX DK 431, ACCRA- GHANA

Manufactured by Reyoung Pharmaceutical Co., Ltd., P.R. China