Gloclav

Co-amoxiclav

Composition:
GLOCLAV 375 mg Film Coated Tablets: Each film coated tablet contains Amoxicillin Trihydrate USP equivalent to Amoxicillin 250mg and Potassium Clavulanate USP equivalent to Clavulanic acid 125mg.
GLOCLAV 625 mg Film Coated Tablets: Each film coated tablet contains Amoxicillin Trihydrate USP equivalent to Amoxicillin 500mg and Potassium Clavulanate USP equivalent to Clavulanic acid 125mg.
GLOCLAV 1 g Film Coated Tablets: Each film coated tablet contains Amoxicillin Trihydrate USP equivalent to Amoxicillin 875mg and Potassium Clavulanate USP equivalent to Clavulanic acid 125 mg.
GLOCLAV 156 mg/ 5 ml powder for oral suspension: Each 5ml contains Amoxicillin Trihydrate USP equivalent to Amoxicillin 125 mg and Potassium Clavulanate USP equivalent to Clavulanic acid 31.25mg.
GLOCLAV 312 mg/ 5 ml powder for oral suspension: Each 5 ml contains Amoxicillin Trihydrate USP equivalent to Amoxicillin 250mg and Potassium Clavulanate USP equivalent to Clavulanic acid 62.5mg.

Properties:
GLOCLAV (Co-amoxiclav) is an oral antibacterial combination consisting of the semi synthetic broad-spectrum antibiotic Amoxicillin and the beta-lactamase enzyme inhibitor Clavulanic acid, which protects amoxicillin from destruction and subsequent loss of antibacterial activity by the beta-lactamase enzyme produced by many Gram-negative and Gram-positive bacteria.
This combination extends the spectrum of amoxicillin to include a wider range of organisms, including many resistant to other beta-lactam antibiotics.
Amoxicillin and clavulanic acid are well absorbed from the gastrointestinal tract following oral administration of GLOCLAV.
GLOCLAV is bactericidal against a wide range of beta-lactamase and non-beta-lactamase producing organisms including:
Gram-positive:
Streptococcus pneumonia, Streptococcus pyogen, Streptococcus viridans, Enterococcus faecalis, Staphylococcus aureus (methicillin-sensitive), Staphylococcus epidermidis, Corynebacterium species, Listeria monocytogenes.
Gram-negative:
Haemophilus influenzae, Haemophilus ducreyi, Escherichia coli, Proteus mirabilis, Proteus vulgaris, Klebsiella species, Branhamella (moraxella) catarrhalis, Salmonella species, Shigella species, Bordetella pertussis, Brucella species, Neisseria gonorrhoea, Neisseria meningitidis, Vibrio cholerae, Pasteurella multocida.
Anaerobes: Gram-positive: Clostridium species, Peptococcus species, Peptostreptococcus species. Gram-negative: Bacteroides species including B. fragilis.

Indications:
GLOCLAV is indicated for treatment of the following bacterial infections due to susceptible organisms:
- Upper respiratory tract infection (including ENT), e.g. tonsillitis, sinusitis, otitis media.
- Lower respiratory tract infections, e.g. acute and chronic bronchitis, lobar and bronchopneumonia.
- Genito-urinary tract infections, e.g. cystitis, urethritis, pyelonephritis, pelvic infections, chancroid, gonorrhoea.
- Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, animal bites, wound infections.
- Bone and joint infections, e.g. osteomyelitis.
- Dental infections, e.g. dentoalveolar abscess.
- Other infections, e.g. puerperal sepsis, septic abortion, intra-abdominal sepsis.

Dosage and Administration:
GLOCLAV may be administered without regards to meals. However, to minimize potential gastrointestinal intolerance, administer at the start of a meal.
Adults and Children over 12 years:
Mild-Moderate infections: One GLOCLAV 375 mg tablet every 8 hours.
Severe infections: One GLOCLAV 625 mg tablet every 8 hours or one Gloclav 1g tablet every 12 hours.
Severe dental infections (but not generally first-line): One GLOCLAV 375 mg tablet every 8 hours for 5 days.
GLOCLAV 375 mg and 625 mg and 1g tablets are not recommended in children of 12 years and under.
Children 12 years and below:
Dosage usually depends on the severity of the infection. Generally, total daily dose should be divided into 3 equal doses to be administered every 8 hours.
A recommended regimen is as follows:
GLOCLAV 156 mg/ 5 ml Suspension:
Children 1-6 years (10-18 kg): 5 ml every 8 hours
Or infants and children up to 6 years 0.8 ml/kg daily in 3 divided doses.
In severe infections, the dose may be increased to 1.6 ml/kg daily in 3 divided doses.
GLOCLAV 312 mg/ 5 ml Suspension:
Children 6-12 years (18-40 kg): 5 ml every 8 hours
Or 0.4 ml/kg daily in 3 divided doses.
In severe infections, the dose may be increased to 0.8 ml/kg daily in 3 divided doses.
Dosage in Renal Impairment:
Adults:
Mild impairment (Creatinine clearance > 30 ml/min): No change in dosage.
Moderate impairment (Creatinine clearance 10-30 ml/min):
One GLOCLAV 375 mg tablet or one GLOCLAV 625 mg tablet every 12 hours.
Severe impairment (Creatinine clearance < 10 ml/min):
Not more than one GLOCLAV 375 mg tablet every 24 hours.
GLOCLAV 625 mg tablets are not recommended.

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Children:
Similar dosing adjustment is required.

Contraindications:
GLOCLAV should not be administered to patients hypersensitive to penicillins, cephalosporins, and other beta-lactams. It is also contraindicated in patients with a previous history of amoxicillin-Clavulanic acid or penicillin-associated jaundice or hepatic dysfunction.

Precautions:
GLOCLAV should be used with care in patients with hepatic impairment.
Changes in liver function tests have been observed in some patients receiving amoxicillin-Clavulanic acid. Hepatic function monitoring is recommended with the use of GLOCLAV in patients with hepatic dysfunction. Cholestatic jaundice, which is usually reversible, and may very rarely be severe, has rarely been reported, either during, or shortly after, the use of amoxicillin-Clavulanic acid.
GLOCLAV should be used with care in patients with moderate or severe renal impairment. Dosage should be adjusted in response to the degree of renal impairment.
GLOCLAV should be given cautiously to patients with gastrointestinal disease as it may lead to pseudomembranous colitis.
Erythematous rashes have been associated with glandular fever in patients receiving amoxicillin. Avoid GLOCLAV if glandular fever is suspected.
Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.
The duration of treatment should be appropriate to the indication and should not usually exceed 14 days.

Use in Pregnancy and Lactation:
As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician.
GLOCLAV may be administered during the period of lactation. With the exception of the risk of sensitization, associated with excretion of trace amounts in breast milk, there are no significant effects to the infants.

Side Effects:
GLOCLAV is well tolerated. Side effects, as with amoxicillin, are uncommon and mainly of mild and transitory nature. The reported adverse effects include diarrhoea, nausea, vomiting, antibiotic-associated colitis (including pseudomembranous colitis), and candidiasis have been reported. Hepatitis and cholestatic jaundice have been reported rarely.
Uriticarial and erythematous rashes sometimes occur. Rarely erythema multiforme (including Stevens-Johnson syndrome), toxic epidermal necrolysis, exfoliative dermatitis and vasculitis have been reported.
Treatment should be discontinued if one of these types of rash appears.
Prolongation of bleeding time, dizziness, headache, convulsions (particularly with high doses or in renal impairment) may occur very rarely.
Superficial staining of the teeth has very rarely been reported with the use of the suspension.

Drug Interactions:
Prolongation of bleeding time and prothrombin time have been reported in some patients receiving amoxicillin-Clavulanic acid. GLOCLAV should be used with care in patients on anti-coagulant therapy.
In common with other broad-spectrum antibiotics, GLOCLAV may reduce the efficacy of oral contraceptives and patients should be warned accordingly.
Concomitant use of GLOCLAV and probenecid is not recommended as probenecid may decrease the renal tubular excretion of amoxicillin and not clavulanic acid.
Concomitant use of allopurinol during treatment with amoxicillin may increase the incidence of allergic skin reactions, however, there are no data on concomitant use of GLOCLAV and allopurinol.

Presentation:
GLOCLAV 375 mg Film Coated Tablets in packs of 20 and 100 FC Tablets
GLOCLAV 625 mg Film Coated Tablets in packs of 20 and 100 FC Tablets
GLOCLAV 1g Film Coated Tablets in packs of 14 FC Tablets
GLOCLAV Dry Syrup 156 mg/5 ml: in bottles of 100 ml.
GLOCLAV Dry Syrup 312 mg/5 ml: in bottles of 100 ml.

Store at room temperature below 25°C, in a dry place, protected from light. After reconstitution of the suspension, store in a refrigerator (but not frozen) and use within 7 days. Shake well before use.

THIS IS A MEDICAMENT

- A Medicament is a product, which affects your health, and its consumption, contrary to instruction, is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not, by yourself, interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

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