Labclav®

Amoxicillin and Potassium Clavulanate (Co-amoxiclav)

Tablets

Broad spectrum antibiotic

COMPOSITION (Active ingredients):

Labclav® 375mg tablets
Each film-coated tablet contains 250mg Amoxicillin and 125 mg Clavulanic acid.

Labclav® 625mg tablets
Each film-coated tablet contains 500mg Amoxicillin and 125mg Clavulanic acid.

Labclav® 1g tablets
Each film-coated tablet contains 875mg Amoxicillin and 125mg Clavulanic acid.
In the above preparations, amoxicillin is present as amoxicillin trihydrate BP and clavulanic acid is present as potassium clavulanate BP.

INDICATIONS:
Labclav® is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in hospital & general practice. The beta-lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other beta lactam antibiotics.

Labclav® is indicated for short-term treatment of bacterial infections at the following sites:

1. Upper respiratory tract infections (including ENT) e.g. Tonsillitis, sinusitis, otitis media.
2. Lower respiratory tract infections e.g. acute and chronic bronchitis, lobar and bronchopneumonia.
3. Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis.
4. Skin and soft tissue infections, e.g boils, abscesses, cellulitis, wound infections.
5. Bone and joints infections e.g osteomyelitis.
6. Dental infections e.g dentoalveolar abscess.
7. Other infections e.g septic abortion, puerperal sepsis, intra-abdominal sepsis.

Labclav® is bactericidal to a wide range of organisms including beta-lactamase producing strains resistant to ampicillin and amoxicillin.

Gram-positive
Aerobes: *Enterococcus faecalis, streptococcus pneumonia, Streptococcus pyogenes, Streptococcus viridans, Staphylococcus aureus,* Coalgulase negative Staphylococci (including *Staphylococcus epidermidis*). Corynebacterium species, *Bacillus anthracis. Listeria monocytogenes.*
Anaerobes: clostridium species, Peptococcus species, Peptostreptococcus.

Gram – negative
Aerobes: *Haemophilus influenza, 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.*

Dosage and administration

Three times a day dosing regimen
Usual dosage for the treatment of infection:
Adults and children over 12 years:

Mild-moderate infections: one **Labclav®** 375mg tablet three times a day.

Severe infections: Two **Labclav®** 375mg tablets or one **Labclav®** 625mg tablet three times a day.

Labclav® 375mg tablets are not recommended in children of 12 years and under, in such cases **Labclav®** suspension is recommended.

Dosage in dental infection (e.g dentoalveolar abscess): Adults and children over 12 years: one **Labclav®** 375mg tablet three times a day for five days.

Dosage in renal impairment:
In patients with mild impairment (creatinine clearance >30ml/min) no change in dosage is recommended. In patients with moderate impairment (creatinine clearance 10-30ml/min) one 375mg tablet 12 hourly is recommended. In patients with severe impairment (creatinine clearance <10ml/min) not more than one 375mg tablet 12 hourly is recommended.

Twice a day dosing regimen
Usual dosages for the treatment of infection
Adults and children over 12 years:

Mild-moderate infections: one **Labclav®** 625mg tablet twice a day.

Severe infections: One **Labclav®** 1g tablet twice a day.

Dosage in dental infections (e.g dentoalveolar abscess): adults and children over 12 years. One **Labclav®** 625mg tablets two times a day for five days.

Labclav® 625mg and 1g tablets are not recommended in children of 12 years and under, in such cases **Labclav®** suspension is recommended.

Dosage in renal impairment:
The **Labclav®** 1 g tablets should only be used in patients with a glomerular filtration rate of>30ml/min.

In patients with mild impairment (creatinine clearance>30ml/min) no change in dosage (i.e either one 625mg tablets bid or one 1g tablet) is recommended.

In patients with moderate impairment (creatinine clearance 10-30ml/min) one 625mg tablet bid is recommended. The 1g tablet should not be administered. In patients with severe impairment (creatinine clearenace< 10ml/min) not more than one 625mg tablet every 24hours is recommended.

Dosage in hepatic impairment:
Dose with caution; monitor hepatic function at regular intervals.

Oral administration
Tablets should be swallowed whole without chewing, if required, tablets may be broken in half and swallowed without chewing. To minimize potential gastrointestinal intolerance, administer at the start of a meal. The absorption of co-amoxiclav is optimized when taken at the start of a meal.
Treatment should not be extended beyond 14 days without review.

CONTRAINDICATIONS:
Penicillin hypersensitivity; attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics, e.g. Cephalosporins.
A previous history of co-amoxiclav or penicillin-associated jaundice/hepatic dysfunction.

PRECAUTIONS:
Changes in liver function tests have been observed in some patients receiving co-amoxiclav. The clinical significance of these changes is uncertain but co-amoxiclav should be used with caution in patients with evidence of hepatic dysfunction. 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. In patients with moderate or severe renal impairment co-amoxiclav dosage should be adjusted as recommended in the dosage and administration section. Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity. Erythematorus rashes have been associated with glandular fever in patients receiving amoxicillin. Co-amoxiclav should be avoided if glandular fever is suspected. Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.

INTERACTIONS:
Prolongation of bleeding time and prothrombin time have been reported in some patients receiving co-amoxiclav.
Co-amoxiclav should be used with care in patients on anti-coagulation therapy. In common with other broad spectrum antibiotics, Co-amoxiclav 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 co-amoxiclav 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 co-amoxiclav and allopurinol.

USE IN PREGNANCY AND LACTATION:
There is limited experience of the use of co-amoxiclav in human pregnancy. As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician. Co-amoxiclav 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 EFFECTS:
Side effects, as with amoxicillin, are uncommon and mainly of a mild and transitory nature.

Gastrointestinal reactions
Effects include diarrhea, 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 Labclav® at the start of meals.

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 co-amoxiclav. 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 beta-lactam antibiotics angioedama, oedema, anaphylaxis, serum sickness-like syndrome and hypersensitivity vasculitis have been reported. Interstitial nephritis can occur rarely.

Haematological effects
As with other beta-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.

OVERDOSAGE
Cases of overdosage with Labclav® 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. Co-amoxiclav may be removed from the circulation by haemodialysis.

THERAPEUTIC CATEGORY: POM (Prescription only medicine).

Storage: Store in a dry place below 30°C. Protect from light. Keep all medicines out of reach of children.

Shelf Life : As per product label

Presentation:
Labclav® 375 mg tablets : Pack of 2 x 10 tablets (10's blister x 2).
Labclav® 625 mg tablets : Pack of 1 x 10 tablets (10's blister x 1), 2 x 10 tablets (10's blister x 2) and 10 x 10 tablets (10's blister x 10)
Labclav® 1 g tablets : Pack of 1 x 10 tablets (10's blister x1) and 7 x 2 tablets (7's blister x 2).

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