KLAVOX®

clavulanate-potentiated amoxycillin

INTRODUCTION

KLAVOX is a formulation of amoxycillin, a bactericidal broad spectrum penicillin, and potassium clavulanate, a progressive and irreversible inhibitor of β–lactamase enzymes. The presence of potassium clavulanate protects amoxycillin from destruction and subsequent loss of antibacterial activity by the β–lactamase enzymes produced by many Gram-negative and Gram-positive bacteria. The spectrum of amoxycillin is thus widened to include organisms normally resistant by virtue of their ability to produce β–lactamase. **KLAVOX** will not only eliminate primary pathogens but also will not be inactivated by non pathogenic β–lactamase producing organisms at the site of infection.

BACTERIOLOGY

KLAVOX is bactericidal to a wide range of Gram-positive and Gram-negative bacteria including many clinically important β–lactamase producing penicillin resistant organisms both in the hospital and general practice environment, including :

Gram-positive : *Aerobes *Staphylococcus aureus, *Staphylococcus epidermidis, Streptococcus pyogenes, Bacillus anthracis, Corynebacterrium species, Streptococcus pneumoniae, Streptococcus viridans, Streptococcus faecalis, Listeria monocytogenes Anaerobes* Clostridium species, Peptococcus species, Peptococcus species.

Gram-negative :
*Aerobes Escherichia coli, Proteus mirabilis, *Proteus vulgaris,* *Klebsiella species, *Salmonella species, *Shigella species, *Bordetella pertussis, *Yersinia enterocolitica, Gardnerella vaginalis,* Brucella species, *Neisseria meningitidis, *Neisseria gonorrhoeae, *Branhamella catarrhalis, *Haemophilus influenzae, *Haemophilus ducreyi, Pastuerella multocida, Campylobacter jejuni, Vibrio cholerae.*
Anaerobes *Bacteroides species including *Bacteroides fragilis*
* including β–lactamase producing strains resistant to ampicillin and amoxycillin.

INDICATIONS

KLAVOX is indicated for the treatment of common bacterial infections where antibiotic therapy is indicated, including:
Upper Respiratory Tract Infections e.g. Sinusitis, tonsillitis, otitis media.
Lower Respiratory Tract Infections e.g. Acute and chronic bronchitis, lobar and bronchopneumonia, empyema, lung abscess.
Skin And Soft Tissue Infections e.g. Boils / abscesses, cellulitis, wound infections, intra-abdominal sepsis.
Genito-Urinary Tract Infections e.g. Cystitis, urethritis, pyelonephritis, septic abortion, puerperal sepsis, pelvic infections, chancroid, gonorrhea.
Other Infections e.g. Osteomyelitis, septicaemia, peritonitis, post-operative infections.

DOSAGE

Adults And Children Over 12 Years

Route	**Dosage**
Oral	Mild-moderate infections: One 375 mg **KLAVOX** tablet three times a day. Severe infections: One 625 mg **KLAVOX** tablet three times a day or two 375 mg **KLAVOX** tablets three times a day

Children
Oral

Children 7-12 years:	10ml **KLAVOX** 156mg syrup three times a day*
or	5ml **KLAVOX** 312mg syrup three times a day*
Children 2-7 years:	5ml **KLAVOX** 156mg syrup three times a day*
Children 9 months - 2 years:	2.5ml **KLAVOX** 156mg syrup three times a day*
Children 0-9 months:	No suitable oral presentation is currently available for this age group.

* In severe infections these dosages may be doubled.
Treatment with **KLAVOX** should not be extended beyond 14 days without review.
Dosage In Renal Impairment
Adults:

	Mild Impairment (Creatinine clearance > 30ml/min)	**Moderate Impairment (Creatinine clearance 10-30ml/min)**	**Severe Impairment (Creatinine clearance < 10ml/min)**
Oral	No change in dosage	375-750mg 12 hourly	Not more than 375mg 12 hourly

Children: Similar reductions in dosage should be made for children.

PREPARATION AND ADMINISTRATION

KLAVOX oral is well absorbed whether taken with or before meals.

KLAVOX syrup: To make up first shake bottle to loosen powder. Then add the volume of water stated on the bottle label and shake well or add water to 2/3 of fill level line on label, shake well and fill up to line. When first reconstituted allow to stand for 5 minutes to ensure full dispersion. Once reconstituted, **KLAVOX** syrup must be stored in a refrigerator and used within 7 days. Shake well before taking each dose.

CONTRAINDICATION

Penicillin hypersensitivity.

PRECAUTIONS

Changes in liver function tests have been observed in some patients receiving **KLAVOX.** The clinical significance of these changes is uncertain but **KLAVOX** should be used with care in patients with evidence of severe hepatic dysfunction. In patients with moderate or severe renal impairment **KLAVOX** dosage should be adjusted as recommended in the "Dosage" section.

USE IN PREGNANCY AND LACTATION

Animal studies with orally and parenterally administered **KLAVOX** have shown no teratogenic effects. The product has been used in human pregnancy in a limited number of cases, with no untoward effect; however, use of **KLAVOX** in pregnancy is not recommended unless considered essential by the physician.
As with all drugs, therapy with **KLAVOX** during pregnancy should be avoided if at all possible, especially during the first trimester.
During lactation, trace quantities of penicillins can be detected in breast milk.

SIDE EFFECTS

Side effects, as with amoxycillin, are uncommon and mainly of a mild and transitory nature.
Diarrhoea, pseudomembranous colitis, indigestion, nausea, vomiting, and candidiasis have been reported. Nausea, although uncommon, is more often associated with higher oral dosages. If gastro-intestinal side effects occur with oral therapy they may be reduced by taking **KLAVOX** at the start of meals.
Urticarial and erythematous rashes sometimes occur but their incidence has been particularly low in clinical trials. An urticarial rash suggest penicillin hypersensitivity and treatment should be discontinued. Erythematous rashes are frequently mild and transient but may be severe when associated with infectious mononucleosis, in which case treatment should be discontinued.
Rare cases of erythema multiforme, Stevens-Johnson syndrome and an occasional case of exfoliative dermatitis have been reported.
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and angioneurotic oedema have been reported in patients on penicillin therapy. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients taking oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. Hepatitis and cholestatic jaundice have been reported.

OVERDOSAGE

Problems of overdosage with **KLAVOX** are unlikely to occur; if encountered they may be treated symptomatically.
KLAVOX may be removed from the circulation by haemodialysis.

AVAILABILITY

375mg **KLAVOX** tablets:	White oval film coated tablets engraved **"KLAVOX"** on one side. Each tablet contains 250mg amoxycillin and 125mg clavulanic acid.
625mg **KLAVOX** tablets:	White oval film coated tablets engraved **"KLAVOX"** on one side. Each tablet contains 500mg amoxycillin and 125mg clavulanic acid.
156mg **KLAVOX** syrup:	Powder for preparing fruit flavoured syrup. When dispensed each 5ml contains 125mg amoxycillin and 31.25mg clavulanic acid.
312mg **KLAVOX** syrup:	Powder for preparing fruit flavoured syrup. When dispensed each 5ml contains 250mg amoxycillin and 62.5mg clavulanic acid.

STORAGE

In oral presentations amoxycillin is present as the trihydrate and clavulanic acid as the potassium salt.
KLAVOX presentations should be stored in a dry place below 25°C. Once reconstituted, **KLAVOX** syrup must be stored in a refrigerator, and used within 7 days. If a dilution of the syrup is required, water should be used.

This is a medicament

- Medicament is a product which affects your health, and its consumption contrary to instructions 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

Council of Arab Health Ministers
Union of Arab Pharmacists

Manufactured by **SPIMACO**
Al Qassim Pharmaceutical Plant
Saudi Pharmaceutical Industries &
Medical Appliances Corporation,
Saudi Arabia.

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