Only for the use of Medical Professionals

Avlomox®

Presentation

Avlomox® 250mg Capsules: Yellow body and maroon cap, both cap and body imprinted with either 'AVLOMOX' or 'ACI'. Each capsule contains Amoxycillin 250mg as Trihydrate BP.

Avlomox® 500mg Capsules: Black body and red cap, both cap and body imprinted with either 'AVLOMOX 500' or 'ACI'. Each capsule contains Amoxycillin 500mg as Trihydrate BP

Avlomox® Powder for Suspension 125mg/5ml: Bottles containing powder for the preparation of 100ml white coloured, banana flavoured suspension; when reconstituted each 5ml contains Amoxycillin 125mg as Trihydrate BP.

Avlomox® DS Powder for Suspension 250mg/5ml: Bottles containing powder for the preparation of 100ml/60ml white coloured, banana flavoured suspension; when reconstituted each 5ml contains Amoxycillin 250mg as Trihydrate BP.

Avlomox® Paediatric Drops: Bottles containing powder for the preparation of 15ml of white coloured, banana flavoured suspension; when reconstituted each 1.25ml contains Amoxycillin 125mg as Trihydrade BP.

Avlomox® 500mg Injection: Vials containing Amoxycillin 500mg as Sodium BP; presented as powder for reconstitution.

Uses

Avlomox® is a broad spectrum antibiotic indicated in a wide range of infections caused by susceptible Gram-positive and Gram-negative organisms. These include:

Lower respiratory tract infections: Pneumonia, acute and chronic bronchitis, lung abscess, empyema, bronchiectasis.

Upper respiratory tract infections: Otitis media, sinusitis, tonsillitis, pharyngitis, laryngitis.

Urinary tract infections: Pyelonephritis, cystitis, urethritis.

Gastro-intestinal infections: Typhoid and paratyphoid.

Severe systemic infections: Septicaemia, septic abortion, endocarditis, intra-abdominal sepsis, puerperal sepsis, osteomyelitis, meningitis.

Skin and soft tissue infections: Cellulitis, infected wounds, carbuncles, furunculosis, abscesses.

Venereal infections: Gonorrhoea, syphilis.

Prophylaxis of endocarditis: Avlomox® may be used for the prevention of bacteremia, associated with procedures such as dental extraction, in patients at risk of developing bacterial endocarditis.

Dosage and administration

Adults (including elderly patients): Oral : 250mg three times daily, increasing to 500mg three times daily for more severe infections.

Injectable: 500mg IM eight hourly (or more frequently if necessary) in moderate infections. (This dose may be given by slow IV injection if more convenient).1g IV six hourly in severe infections.

Children: Oral: Upto 10 years of age: 125mg three times daily, increasing to 250mg three times daily for more severe infections.

Under 2 years of age: 1/4 of the adult dose.

Injectable: 50 - 100mg/kg body weight IM or IV (depending on the severity) in three to four equal divided doses.

Specific dosage recommendations:

Acute cystitis/Bacteriuria: A single dose of 3g.

Typhoid and Paratyphoid: Adult dosage: 4g daily in divided doses for 14-21 days.

Children dosage: 100mg/kg bodyweight daily in divided doses for 14-21 days.

Typhoid carrier states: 3-4g daily in divided doses for a minimum of 1 month.

Gonorrhoea: A single dose of 3g.

Syphilis : A dosage of 250mg every 6 hours has been used in all stages of syphilis. Duration of treatment varied from 4 weeks upto 5 months according to serological response.

Simple acute urinary tract infection: Two 3g doses with10-12 hours between the doses.

Dental abscess: Two 3g doses with 8 hours between the doses.

Severe or recurrent acute otitis media: 3 to 10 years : 750mg twice a day for two days may be used as an alternative course of treatment.

Prophylaxis of Endocarditis: Adults: 3g orally,1 hour before and 6 hours after dental procedure. Children: 1/2 of the adult dose. Patients with prosthetic heart valves or with a history of endocarditis will require gentamicin in addition.

Administration

Intravenous: Dissolve 500 mg in 10ml Water for Injection BP.

Avlomox® Injection, suitably diluted, may be injected directly into a vein or the infusion line over a period of 3-4 minutes.

Intravenous Infusion: Solutions may be prepared as described for intravenous injections and then added to an intravenous solution in a minibag or in-line burette and administered over a period of 1/2-1 hour. Alternatively, using a suitable reconstitution device, the appropriate volume of intravenous fluid may be transferred from the infusion bag into the vial and then drawn back into the bag after dissolution.

500mg: Add 2.5ml Water for Injections BP and shake vigorously.

If pain is experienced on intramuscular injection, a sterile 1% solution of lignocaine hydrochloride or 0.5% solution of procaine hydrochloride may be used in place of water for injections.

A transient pink colouration or slight opalescence may appear during reconstitution. Reconstituted solutions are normally a pale straw colour.

Contra-indications, warnings, etc.

Contra-indications: Penicillin hypersensitivity.

Use in pregnancy and lactation: Animal studies with Amoxycillin have shown no teratogenic effects. It's suitability in human pregnancy has been well documented in clinical studies. When antibiotic therapy is required during pregnancy, Amoxycillin may be considered appropriate. During lactation, trace quantities of Amoxycillin can be detected in breast milk.

Side-effects: Side-effects as with other penicillins, are uncommon and mainly of a mild and transitory nature; they may include diarrhoea, indigestion, or occasionally rash, either urticarial or erythematous. In common with other beta-lactam antibiotics angioedema and anaphylaxis have been reported.

Overdosage: Gross overdosage will produce very high urinary concentrations. Problems are unlikely if adequate fluid intake and urinary output are maintained; however, crystalluria is a possibility. More specific measures may be necessary in patients with impaired renal function, the antibiotic is removed by hemodialysis.

Pharmaceutical precautions

Store in a cool, dry place.

Avlomox® DS, Avlomox® Powder for Suspension and Avlomox® paediatric drops should be freshly prepared.

Prepared Suspension is to be consumed within 7 days of preperation.

When prepared for intramuscular or direct intravenous injections, Avlomox® should be administered immediately after reconstitution. The stability of Avlomox® in various infusion fluids is dependent upon the concentration and temperature.

Avlomox® should not be mixed with blood products, other proteinaceous lipid emulsions.

If Avlomox® is prescribed concurrently with aminoglycoside the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set because loss of activity of the aminoglycoside can occur under these conditions.

Package quantities

Avlomox® 250mg Capsules: Carton of 100 capsules in aluminium strips.

Avlomox® 500mg capsules: Carton of 40 capsules in aluminium strips.

Avlomox® Powder for Suspension 125mg/5ml: Bottle of 100ml.

Avlomox® DS Powder for Suspension 250mg/5ml: Bottle of 100ml.

Avlomox® Paediatric Drops: Bottle of 15ml.

Avlomox® 500mg Injection: Box containing 1 vial of 500mg and 1 ampoule of 5ml water for Injection BP for dilution.

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