

Impedox[®]

Doxycycline

Presentation

Impedox[®] Capsule: Each capsule contains Doxycycline 100 mg as Hydrochloride BP.

Uses

Impedox[®] is clinically effective in the treatment of a variety of infections caused by a wide range of Gram-negative and Gram-positive bacteria as well as certain other microorganisms.

Genito-urinary tract infections: Cystitis, urethritis, pyelonephritis caused by susceptible strains of *Escherichia coli*, *Neisseria gonorrhoea*, *Klebsiella-Enterobacter group*, *Staphylococcus species* and *Chlamydia trachomatis*.

Soft tissue infections: Infected traumatic and postoperative wounds, furunculosis, impetigo cellulitis, abscess and paronychia.

Pneumonia: **Impedox[®]** is effective against single and multilobe pneumonia and broncho-pneumonia.

Other respiratory tract infections: Bronchitis, tonsillitis, pharyngitis, otitis media and sinusitis.

As **Impedox[®]** in one of the tetracycline group of antibiotics, it may be expected to be useful in the treatment of infections which respond to other tetracyclines such as:

Gastro-intestinal infections: Caused by susceptible strains of such organisms as *Shigella species*, *Salmonella species*, *Entamoeba histolytica* and enteropathogenic *E. coli*.

Ophthalmic infections: Caused by susceptible strains of *staphylococci*, *gonococci* and *H. influenzae*. **Impedox[®]** is indicated for the treatment of inclusion conjunctivitis either alone or in combination with topical agents.

Impedox[®] is also suitable in the treatment of trachoma.

Miscellaneous: Trigonitis and prostatitis caused by *Proteus species*. Psittacosis, certain other infections caused by susceptible strains of *Bacteroides species*, *Brucella species* (in combination with streptomycin) and *Bordetella pertussis*. *Calymmatobacterium granulomatis*, *spirochaetes (Treponema species)*, *Bacillus anthracis*, *Neisseria meningitidis* and *Clostridium welchii*.

Impedox[®] may be a useful adjunct to amoebicides in the treatment of acute intestinal amoebiasis. Further, **Impedox[®]** may be useful in the treatment of *Acne vulgaris* and *Acne conglobata*.

Dosage and administration

The recommended adult dose of **Impedox[®]** is 200 mg on the first day of treatment which can be given as a single dose or it can be divided into two 100 mg doses with a 12 hour interval followed by a 100 mg/day maintenance dose. For more severe infections, especially chronic urinary tract infections, a daily dose of 200 mg should be administered during the period of treatment or may be given as advised by the physician.

Impedox[®] is not recommended for children under 12 years of age.

Treatment should be continued for at least 24 to 48 hours beyond the period when symptoms and fever have abated. In the specific case of streptococcal infections, treatment should be continued for 10 days in order that the development of glomerulonephritis or rheumatic fever is prevented.

Primary and secondary syphilis: A recommended daily dosage of 300 mg in divided doses to be administered for at least 10 days or as directed by the physician.

Acute gonococcal infections in the adult female: A dosage schedule of 100 mg twice a day to be continued until cure is effected.

Typhus of the louse-born variety has been successfully treated with a single dose of 100 to 200 mg depending on the severity of infection.

Capsule forms of the tetracycline series of drugs are liable to cause oesophageal irritation and ulceration. Administration of adequate amounts of fluid is therefore recommended to combat this problem. If however, gastric irritation does occur, **Impedox**[®] can be given with food or milk.

Concurrent treatment: Patients taking **Impedox**[®] should not simultaneously ingest antacids containing magnesium, aluminium or calcium salts as these impair absorption. Studies indicate that doxycycline at usual dosage in patients with renal impairment does not lead to excessive accumulation of the antibiotic in the body.

Contraindications, warnings, etc.

Contraindications: Known hypersensitivity to tetracyclines.

Warnings: Tetracyclines may cause a yellow to brown discoloration of the teeth and enamel hypoplasia in the developing foetus or child and therefore, **Impedox**[®] should only be administered if considered essential to pregnant or lactating women and to children under twelve years of age only on advice of a registered physician. Tetracyclines have been reported as causing photosensitivity and allergic skin reactions. Patients should be advised to avoid direct exposure to natural or artificial sunlights and that treatment should be discontinued at the first signs of skin discomfort.

Precautions: Where syphilis is suspected as co-existing with gonorrhoea, proper diagnostic procedures should be utilised including darkfield examinations. Monthly serological tests in such cases should be performed for at least four months. Tetracyclines depress plasma prothrombin activity, therefore reduced dosages of concurrent anti-coagulants may be required.

Adverse reactions: Due to the fact that doxycycline is almost completely absorbed, gastro-intestinal side-effects are infrequent.

Gastro-intestinal: Diarrhoea, nausea, vomiting and anorexia may occur and as with all antibiotics, over growth of resistant organisms may cause glossitis, stomatitis, vaginitis or staphylococcal enteritis. Supra-infection may occur rarely.

Skin: Maculopapular and erythematous rashes. Exfoliative dermatitis has been reported but is uncommon.

Photo-sensitivity may occur.

Hypersensitivity reactions: Anaphylaxis, anaphylactoid purpura, angioneurotic oedema, urticaria, pericarditis and exacerbation to systemic lupus erythematosus. Bulging fontanelles in infants and benign intracranial hypertension in adults have been reported. Treatment should cease if evidence of raised intracranial pressure develops.

Blood: Thrombocytopenia, hemolytic anaemia, eosinophilia and neutropenia have all been reported with tetracyclines.

Overdose and toxic effects: No specific antidote. Gastric lavage plus appropriate supportive treatment. Toxic effects are usually due to hypersensitivity and should be treated as such.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light.

Package quantities

Impedox[®] Capsule: Carton of 100 capsules in blister.

® Registered Trade Mark



ACI Limited

Narayanganj, Bangladesh