Beatacycline

250 mg capsule

DESCRIPTION

Beatacycline Capsule 250mg
A size 2, plain, orange/yellow colour capsule containing Tetracycline HCl 250mg per capsule. Gelatin for Capsule: Bovine source certified with Malaysia's Halal Certification

INDICATIONS

Beatacycline is the drug of choice in rickettsial, clamydial and mycoplasmal infections. It is widely used as part of regimens for pelvic inflammatory disease and genitourinary tract infections. Beatacycline is usually used for the treatment of choice in relapsing fever and in the early stages of Lyme disease. It is also in the oral treatment of acne and rosacea and skin and soft tissue infections. It may be of benefit in the treatment of melioidosis and mouth infections, especially in destructive forms of periodontal disease. Beatacycline are often used as adjunct therapy in the treatment of brucellosis, gonorrhoea with concomitant chlamydial infections, falciparum malaria resistant to chloroquine, severe amoebic dysentery and Dientamoeba fragilis infections. It is also as an alternative to other drugs in
the treatment of tularaemia, bronchitis, gastroenteritis, granuloma inguinale, leptospirosis, syphilis and yaws.

PHARMACODYNAMICS

Tetracycline is taken up into sensitive bacterial cells by an active transport process. Once within the cell they bind reversibly to the 30S subunit of the ribosome, preventing the binding of aminoacyl transfer RNA(tRNA) to the messenger RNA(mRNA) ribosome complex and inhibiting protein synthesis and hence cell growth. Bacterial cell wall synthesis is not inhibited. Although tetracycline also inhibit protein synthesis in mammalian cells, they are not actively taken up, permitting selective effects on the infecting organism.

PHARMACOKINETICS

Most tetracyclines are incompletely absorbed from the gastrointestinal tract, about 60% - 80% of a dose of tetracycline usually being available. The degree of absorption is diminished by the presence of divalent of trivalent metal ions with which tetracycline forms stable insoluble complexes and to a variable degree by milk or food. Formulation with phosphate, as in Beatacycline P Suspension 125, may enhance absorption of tetracyline. Peak plasma concentrations occur about 1-3 hours after ingestion.
About 20% - 65% of tetracycline is bound to plasma proteins. It is widely distributed throughout the body tissue and fluids, including bile, sinus secretions, and synovial, pleural, ascitic, and gingival crevicular fluids. Cerebrospinal fluid (CSF) concentrations are relatively low , but may be raised if the meninges are inflamed. Tetracycline is retained at sites of new bone formation and recent calcification, liver, spleen, tumour and in developing teeth. Tetracyclines appear in the milk of nursing mother where concentrations may be 60% or more of those in the plasma. They diffuse across the placenta and appears in the foetal circulation in concentration of about 25% - 75% of those in the maternal blood. The half - life of tetracycline has been reported to be between 6-11 hours, but in anuric patients, the half - life is between 57-108 hours. The tetracycline is excreated in the urine and faeces. Up to 55% an oral dose is eliminated unchanged in the urine. Urinary excretion is increased if urine is alkalinised. Tetracyclines are excreted in bile where
concentrations 5-25 times those in plasma can occur. Since there is some enterohepatic reabsorption complete elimination is slow. Tetracyclines are slowly removed by hemodialysis. Peritoneal dialysis does not effectively remove tetracyclines

DOSAGE

Adults
All infections due to Group A beta-haemolytic streptococci should be treated for at least 10 days.
Adults (including the elderly) and children over 12 years: The minimum recommended dosage is 250mg every six hours.Therapeutic levels are attained more rapidly by the administration of 500mg initially, followed by 250mg every six hours. For severe infections, the dosage may be increased to 500mg every six hours.
Streptococcal infections: A therapeutic dose of tetracycline should be administered for at least 10 days.
Treatment of acne vulgaris and severe rosacea: 250-500mg daily in single or divided doses should be administered for at least three months.
Brucellosis: 500mg tetracycline four times daily accompanied by streptomycin.
Uncomplicated gonococcal infections (except anorectal infections in man): 500mg four times daily for 7 days
Primary and secondary syphilis: 500mg four times daily for 15 days.
Syphilis of more than one year's duration, (latentsyphilis of uncertain or more than one year's duration, cardiovascular or late benign syphilis) except neurosyphilis: 500mg, four times daily for 30 days
Acute epididymo- orchitis caused by Chlamydia trachomatis, or Neisseria gonorrhoea: 500mg four times daily for 10 days
Uncomplicated urethral, endocervical or rectal infection caused by Chlamydia trachomatis: 500mg four times daily for 7 days
Renal impairment: In general tetracyclines are contraindicated in renal impairment and the dosing recommendations only apply if use of this class of drug is deemed absolutely essential. Total dosage should be decreased by reduction of recommended individual doses and/or by extending time intervals between doses.

Elderly
Usual adult dose.

Children under 12 years
Contraindicated in this age group.

OVERDOSAGE

Symptoms
- There may be nausea and vomiting.
- Crystalluria and haematuria may occur following very large doses.
- Hypersensitivity reactions may occur.

Treatment
There is no specific antidote.
- Gastric decontamination is not necessary.
- Give oral fluids for severe vomiting and diarrhoea if required.
- Manage anaphylaxis reactions conventionally.
- Single brief convulsions do not require treatment. If frequent or prolonged control with intravenous diazepam orlorazepam.
- General symptomatic therapy as indicated by the patient's clinical condition.

PREGNANCY AND LACTATION

Pregnancy and Reproduction : Tetracycline crosses the placenta; use is not recommended during the last half of pregnancy since tetracycline may cause permanent discoloration of teeth, enamel hypoplasia, and inhibition of skeletal

growth in the foetus. In the addition, fatty infiltration of the liver may occur in pregnant women.
(*FDA Pregnancy Category D)*
Breast-feeding : Tetracycline is excreted in breast milk; although tetracycline may form nonabsorbable complexes with breast milk calcium, use is not recommended because of the possibility of their causing permanent discoloration of teeth, enamel hypoplasia, inhibition of skeletal growth, photosensitivity reactions and oral and vaginal thrush in infants.

SIDE EFFECTS

Gastrointestinal effects like diarrhoea, nausea or vomiting can follow oral administration of Beatacycline due to irritation of the mucosa. Other common side effects included dry mouth, glossitis, stomatitis and dysphagia; CNS toxicity and photosensitivity. Tetracyclines are deposited in deciduos and permanent teeth during their formation, causing discoloration and enamel hypoplasia. They are also deposited in calcifying areas in bone and the nails and interfere with bone growth when given in therapeutic doses to young infants or pregnant women. Oral candidiasis, vulvovaginis and pruritus ani occur occasionally, mainly due to overgrowth of candida albicans. There may also be overgrowth of resistant coliform organisms, such as Pseudomonas and protus spp., causing diarhoea. More serious superinfections with resistant staphylococci causing enterocolitis and also pseudomembranous colitis have occasionally been reported . Hypertrophy of the papilla (darkened or discoloured tongue) occurs less frequently. An increased intracranial pressure and bulging fontanelles in infants has been reported. Hypersensitivity to tetracycline is much less common but do occur; anaphylaxis has occured very rarely. Abnormal pigmentations of the skin and eye, hemolytic anemia, eosonophilia, neutrapenia, thrombocytopenia and hypoprothrombinemia has occured rarely. Permanent discolouration of the cornea has been reported in infants born to mother given tetracycline in high doses during pregnancy, Myopia in patients taking the drug may be due to transient hydration of the lens. A Jarish- Herxheimer-like reaction has been reported in patients with relapsing fever treated with tetracycline. Severe and sometimes fatal hepatotoxicity associated with fatty changes in the liver and pancreatitis has been reported in pregnant women and in patients with renal function impairment.

CONTRAINDICATIONS

Tetracycline is contraindicated in patients with a history of hypersensitivity to any tetracyclines as cross-sensitivity may occur. It should be avoided in patients with systemic lupus erythematosus, severe renal impairment and pregnancy due to the risk of hepatotoxicity in the mother as well as the effects on the developing foetus. Use in pregnancy, potentially during breast- feeding and in children up to the age of 8 may result in impaired bone growth and permanent discoloration of the child's teeth.

DRUG INTERACTIONS

Tetracycline enchances the effective and/ or toxicity of lithium, digoxin, theophyline, oral anticoagulants, ergot alkoids and methotrexate. Potentially hepatotoxic drug including erythromcyin, chloramphenicol, isoniazid and sulphonemides should not be given concomitantly. The risk of nephorotoxicity may be increased if given with methoxyflurane, diuretics or other potentially nepthorotoxic medications.
The absorption of tetracycline is reduced by divalent and trivalent cations such as aluminium, bismuth, calcium, iron, magnesium and zinc. Concomitant administration of tetracycline with antacids, sucralfate, iron and calcium supplements, chloline and magnesium salicylates, some foods such as milk and dairy products, other preparations containing such cations and sodium bicarbonate result in formation of nonabsorbable complexes. Concurrent use with cholestyramine colestinal may result in binding of oral tetracycline, thus impairing their absorption.
Long term use of tetracyclines with estrogen containing oral contraceptives may result in reduced contraceptive reliability and increased incidence of breakthrough bleeding. Use of an alternate or additional method of contraception is advisable. An increased incidence of benign intracranial hypertension had been reported when retinoids and tetracycline were given together.
Since bacteriostatic drugs may interfere with the bactericidal effects of penicillin in the treatment of meningitis or in other situations where a rapid bactericidal effect is necessary, it is best to avoid concurrent therapy with Beatacycline.

PRECAUTIONS

Care should be taken if tetracyclines are given to patients with impaired liver function and high doses should be avoided. Patients who may be exposed to direct sunlight should be warned of the risk of photosensitivity. Care is advisable in patients with myasthenia gravis, who may be at risk of neuromuscular blockade.
Usual therapeutic doses given to patients with renal disease increase the severity of uraemia, with increased excretion of nitrogen and losses of sodium, accompanied by acidosis and hyperphosphataemia.
Beatacycline may produce false positive elevations of urinary catecholaminies because of interferences of fluorescence in the Hingerty method. Serum concentrations of alanine aminotransferase (ALT [SGPT]), alkaline phosphatase amylase, aspartate aminotransferase (AST[SGOT]) and bilirubin may be increased. Antianabolic effects of tetracycline may cause in increase in blood urea nitrogen (BUN) concentrations; in patients with significantly impaired renal function, increased serum concentrations of tetracycline may lead to azotemia, hyperphosphatemia and acidosis.
Geriatrics :
No information is available on the relationship of age to the effects of tetracyclines in geriatric patients

PRESENTATION

Beatacycline Capsule 250mg
100 x 10's (blister pack)

STORAGE CONDITIONS AND SHELF LIFE

Store in a dry place below 30°C.
Protect from light.
Keep out of reach of children.
Jauhkan dari kanak-kanak.
Shelf life: Please refer to outer package.
Tetracycline should be given one hour before or two hours after meals, since food and some dairy products interfere with absorption.
The tablets should be taken with a good drink of water.
Route of administration: Oral.
Therapy should be continued for up to three days after symptoms have subsided.

Product Registration Holder:
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