Borymycin®
Capsule 50mg
Capsule 100mg

Ingredient(s):
Each capsule contains:
Minocycline Hydrochloride ..... 50mg(potency)
Minocycline Hydrochloride ..... 100mg(potency)

Pharmacodynamics:
Minocycline Hydrochloride acts similarly as the other Tetracyclines. It exerts its bacteriostatic effect by inhibiting bacterial protein synthesis. It appears to be generally 2 to 4 times more potent than Tetracycline against Gram-positive and Gram-negative bacteria, 8 times more potent against *S. viridans*, but shares equally low potency against *S. faecalis*. It is especially effective against *Mycobacterium marinum*.

Pharmacokinetics:
1. Minocycline has a similar spectrum of activity to other tetracycline but in particular is more effective against Staphylococcus aureus and Norcardia. It is often active against penicillin-resistant strains of Staphylococcus aureus and against strain of those organism that are resistant to other tetracycline.
2. Minocycline is almost completely absorbed after oral administration; its absorption is not appreciably influence by the presence of food or milk. Absorption may, however, by decreased by the simultaneous administration of iron-containing hematinic or antacids.
3. It is widely distributed in human tissue and fluids.
4. The serum half-life ranges from 11 ~ 17 hours following a single 200mg dose.

Indication(s):
Borymycin Capsule is indicated in the treatment of the following infections caused by susceptible strains: Respiratory tract infections caused by *Mycoplasma pneumoniae*; Psittacosis due to *Chlamydia psittaci*; Trachoma caused by *Chlamydia trachomatis*, although the infectious is not always eliminated, as judged by the immunofluorescence; Inclusion conjunctivitis caused by *Chlamydia trachomatis*; Nongonococcal urethritis in adults caused by *Ureaplasma urealyticum* or *Chlamydia trachomatis*; Chancroid due to *Haemophilus ducreyi*; Cholera caused by *Vibrio cholerae*.

Minocycline is indicated for treatment of infections caused by the following Gram-negative microorganisms, when bacteriologic testing indicates appropriate susceptibility to the drug: *Escherichia coli*; *Enterobacter aerogenes*; *Shigella* species; *Acinetobacter* species; Respiratory tract infections caused by *Haemophilus influenzae*; Respiratory tract and urinary tract infections caused by *Klebsiella* species.

Minocyline is indicated for treatment of infections caused by the following Gram-positive microorganisms, when bacteriologic testing indicates appropriate susceptibility to the drug: Upper respiratory tract infections caused by *Streptococcus pneumoniae*; Skin and skin structure infections caused by Minocycline-sensitive organism; Uncomplicated urethritis in men due to *Neisseria gonorrhoeae* and for the treatment of other gonococcal infections when penicillin is contraindicated.

Minocycline is an alternative drug in the treatment of the following infections: Infections in women caused by *Neisseria gonorrhoeae* ; Syphilis caused by *Treponema pallidum*; Listeriosis due to *Listeria monocytogenes*; Anthrax caused by *Bacillus anthracis*; Infections caused by *Clostridium* species; In severe acne, Minocycline may be used as an adjunct therapy.

Oral Minocycline is indicated in the treatment of asymptomatic carriers of *Neisseria meningitidis* to eliminate meningococci from the nasopharynx. It is recommended that the prophylactic use of Minocycline be reserved for situations in which the risk of meningococcal meningitis is high.

Oral Minocycline also has been used in the treatment of infections caused by *Mycobacterium marinum*.

Dosage and Administration:
Adults : Initial dose is 200mg, followed by 100mg every 12 hours.

1. For gonorrhea patients sensitive to penicillin: 200mg initially, then 100mg every 12 hours for a minimum of 4 days. Post-therapy culture within 2-3 days is necessary.
2. For *Neisseria meningitidis* carrier (asymptomatic) : 100mg every 12 hours for 5 days.
3. For *Mycobacterium marinum* infection : 100mg every 12 hours for 6-8 weeks. Optimaldose is not yet established.
4. For uncomplicated urethral, endocervical or rectal infections caused by *Chlamydia trachomatis* and *Ureaplasma urealyticum* : 100mg twice daily for at least 7 days.
5. For uncomplicated gonococcal urethritis in men : 100mg twice a day for 5 days.

Children over 12 years of age : Initial dose of 4mg/kg of body weight followed by 2mg/kg every 12 hours. Dosage reduction is not necessary in patients with renal impairment. May be taken with food or milk if gastrointestinal irritation occurs. To be dispensed on physician's prescription.

Route of administration:
Oral administration

Contraindication(s):
1. Hypersensitivity to any of the Tetracyclines.
2. Minocycline, like other Tetracycline-class antibiotics, can cause fetal harm when administered to a pregnant woman. If any Tetracycline is used during pregnancy or if the patients become pregnant while taking these drugs, the patients should be considered of the potential hazard to the fetus.
3. Tetracyclines are excreted in human milk. Because of the potential for serious side effects in nursing infants from the Tetracyclines, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.
4. In complete renal failure, Minocycline, like other Tetracycline-class, should be discontinued as systemic accumulation of the drug may lead to liver toxicity.
5. Generally should not be used by children under 12 years of age, unless other drugs are ineffective or are contraindicated, because it may cause permanent discoloration of the teeth, enamel hypoplasia, and inhibition of linear skeletal growth.

Precaution(s) / Warning(s):
1. Borymycin Capsule should not be used during pregnancy and lactation. It may cause permanent

discoloration of the teeth, enamel hypoplasia, and inhibition of skeletal growth in the fetus or linear skeletal growth in infants.

2. Prolonged or repeated therapy may result in bacterial or fungal overgrowth of nonsusceptible organisms. If superinfection occurs, the antibiotic should be discontinued and appropriate therapy instituted.
3. Degradation products of Minocycline are highly nephrotoxic and on occasion may produce Fanconi-like syndrome. Therefore, caution should be taken not to use outdated products.
4. Care is advisable in patients with myasthenia gravis who may be at risk of neuromuscular blockade.
5. Increased sensitivity of skin to sunlight may occur.
6. Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
   Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) including fatal cases have been reported with minocycline use. DRESS, which often occurs several weeks after initiation of treatment, consists of a combination of three or more of the following: cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, fever, lymphadenopathy, and one or more systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and pericarditis. Discontinue minocycline if DRESS is suspected.
7. Autoimmune: isolated cases of systemic lupus erythematosus (SLE) have been reported. Also, minocycline is capable of aggravating the symptoms associated with lupus erythematosus. Therefore, caution should be taken when administering the drug to patients with this disease. If patients develop signs or symptoms of SLE, or suffer exacerbation of pre-existing SLE, minocycline should be discontinued.
8. Hepatic Dysfunction: Hepatoxicity has been reported with minocycline hydrochloride; therefore, minocycline should be used with caution in patients with hepatic dysfunction and in conjunction with alcohol or other hepatotoxic drugs.

Drug Interactions:
Penicillin interferes the bacterial action of Minocycline; antacids, iron, sodium bicarbonate, colestipol may impair absorption; may require reduced dose of anticoagulant if concomitantly administered; may decrease effect of oral contraceptives; may enhance methoxyflurane-induced nephrotoxicity.

Pregnancy and Lactation:
Borymycin Capsule should not be used during pregnancy and lactation. It may cause permanent discoloration of the teeth, enamel hypoplasia, and inhibition of skeletal growth in the fetus or linear skeletal growth in infants.

Side Effect(s) / Adverse Reaction(s):
1. Gastrointestinal - Anorexia, nausea, vomiting, diarrhea, stomatitis, glossitis, enterocolitis, pruritus ani, constipation, dyspepsia, dysphagia and inflammatory lesions (with monilial overgrowth) in the anogenital region, increases in liver enzymes and rarely hepatitis and acute liver failure have been reported. Rare instances of esophagitis and esophageal ulceration have been reported in patients taking the tetracycline-class antibiotics in capsule and tablet form. Most of these patients took the medication immediately before going to bed. Very rare incidence of pseudomembranous colitis has been reported.
2. Dermatologic - Maculopapular and erythematosus rashes, photosensitivity, blue-gray pigmentation of the skin and mucous membrane.
3. Hypersensivity - Urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis and serum sickness-like reactions, severe headache, impairment of vision and papilledema.
4. CNS - Lightheadedness, dizziness and vertigo.
5. Blood - Haemolytic anemia, thrombocytopenia, neutropenia and eosinophilia have been reported.
6. Bulging fontanelles in infants and benign intracranial hypertension in adults have been reported.
7. Skin and subcutaneous tissue disorders: Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
8. Autoimmune: Lupus-like syndrome, cases of exacerbation of systemic lupus erythematosus. Lupus-like syndrome consists of positive antinuclear antibody; arthralgia, arthritis, joint stiffness or joint swelling; and one or more of the following: fever, myalgia, hepatitis, rash vasculitis.

Symptoms and Treatment for Overdosage, and Antidote(s):
There is no specific antidote for its overdose; management of the patient should therefore consist of symptomatic and supportive therapy.

Storage Condition(s):
Store at temperature below 30°C. Protect from light and moisture.

Product Description:
Borymycin® Capsule 50mg: A #4 pink cap and body hard gelatin capsule, containing yellow powder.
Borymycin® Capsule 100mg: A size #2 gray blue color cap and orange body hard gelatin capsule.

Shelf-Life:
3 years from the date of manufacture.

Packing(s):
Borymycin® Capsule 50mg:
Blister packing of 10's x 10 and 10's x 50.

Borymycin® Capsule 100mg:
Blister packing of 10's x 10.

Y. S. P.®
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