BORYMYCIN CAPSULE 50MG

Item Code	: Draft 24 Sep 2021
PM Code	: Ins.P BRC5 (S)
Measurement(mm) ± 2mm	: 260(L) x 110(W)
CURSOR (ATTACHMENT 1)	: mm
CURSOR (ATTACHMENT 2)	: mm
Colour of Artwork	: K 100
Source of Artwork	: MAC 3 / CC

Ingredient(s):
Each capsule contains:
Minocycline 50mg (as Minocycline HCl)

Excipients:
Corn Starch, Magnesium Stearate and Empty Gelatin Capsule (Gelatin, Titanium Dioxide, FD&C Red No. 3 & FD&C Yellow No. 6)

Pharmacology (Summary of Pharmacodynamic and Pharmacokinetics):
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.

Minocycline is almost complete absorbed after oral administration; its absorption is not appreciably influenced by the presence of food and milk. Absorption may, however, be decreased by the simultaneous administration of iron-containing hematinic or antacids. It is widely distributed in human tissues and fluids. 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 infection caused by susceptible strains:
Respiratory tract infections caused by *Mycoplasma pneumoniae*; Psittacosis due to *Chlamydia psittaci*; Trachoma caused by *Chlamydia trachomatis*, although the infectious agent is not always eliminated, as judged by immunofluorescence; Inclusion conjunctivitis caused by *Chlamydia trachomatis*; Nongonococcal urethritis in adult 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 microorganism, when bacteriologic testing indicates appropriate susceptibility to the drug: *Escherichia coli; Enterobacter aerogenes; Shigella species; Acinetobacter species*; Respiratory tract infections caused by *Haemophilus influenza*; Respiratory tract and urinary tract infections caused by *Klebsiella species*.
Minocycline is indicated for treatment of infection caused by the following gram-positive microorganism, 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 gonorrheae* 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 gonorrheae*; 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 Mycobcterium marinum infection: 100mg every 12 hours for 6 ~ 8 weeks. Optimal dose 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.

Contraindication(s):
1. Hypersensitivity to any of the Tetracycline.
2. Minocycline, like other tetracycline-class antibiotics, can caused 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. Tetracycline is excreted in human milk. Because of the potential for serious side effects in nursing infants from the tetracycline, 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 in 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.

Side Effect(s) / Adverse Reaction(s):
1. Gastrointestinal - Anorexia, nausea and vomiting, diarrhea, epigastric distress, sore throat, black hairy tongue, esophageal ulcers and inflammatory lesions in the anogenital region.

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2. Dermatologic - Maculopapular and erythematous rashes, photosensitivity, blue-gray pigmentation of the skin and mucous membrane.
3. Hypersensitivity- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis, exacerbation of systemic lupus erythematosus and serum sickness-like reactions, severe headache, impairment of vision and papilledema.
4. CNS - Lightheadedness, dizziness and vertigo.
5. Blood - Agranulocytosis, haemolytic anemia, thrombocytopenia, neutropenia and eosinophilia have been reported.
6. Bulging fontanelles in infants and benign intracranial hypertension in adults have been reported.

Precaution(s) / Warning(s):
1. Borymycin Capsule should not be used during pregnancy and lactation. It may caused 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 non-susceptible organism. If superinfection occur, the antibiotic should be discontinued and appropriate therapy instituted.
3. Degradation product of Minocycline are highly nephrotoxic and on occasion may produce Falconi-like syndrome. Therefore, caution should be taken not to used outdated products.
4. Should be avoided in patients with systemic lupus erythematosus as exacerbation have been reported.
5. Care is advisable in patients with myasthenia gravis who may be at risk of neuromuscular blockade.
6. Increased sensitivity of skin to sunlight may occur.
7. Benign intracranial hypertension (or pseudotumour cerebri) has very rarely been reported in adults. These signs disappeared rapidly when the drug was discontinued.
8. Administration of isotretinoin or other systemic retinoids or retinol should be avoided shortly before, during, and shortly after minocycline therapy. Each of these agents used alone has been associated with benign intracranial hypertension.

Interaction with Other Medicaments:
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 caused permanent discoloration of the teeth, enamel hypoplasia, and inhibition of skeletal growth in the fetus or linear skeletal growth in infants.

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

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

Storage Condition(s):
Keep in a tight container. Store at temperature below 30°C. Protect from light and moisture.

Packing(s):
A #4 pink cap and body hard gelatin capsule, containing yellow powder.
Plastic bottle of 100's and 300's.
Blister packing of 10's x 10 and 10's x 50.
(Not all presentations may be available locally).

L
260mm
(±2mm)

Y. S. P.®

Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
Lot 3, 5 & 7, Jalan P/7, Section 13,
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Date of revision: 24 Sep 2021

W
110mm (±2mm)