Saga®

Sparfloxacin INN 200 mg

Composition:
Saga™: Each film coated tablet contains sparfloxacin INN 200 mg.

Chemistry:
Sparfloxacin is a synthetic broad spectrum antimicrobial (aminodifluoroquinolone). Its empirical formula is $C_{19}H_{22}F_2N_4O_3$.

Pharmacokinetics:
Absorption: Sparfloxacin is well absorbed following oral administration with an absolute oral bioavailability of 92%. The mean maximum plasma Sparfloxacin conc. following a single 400 mg oral dose is approximately 1.3 mcg/ml (0.2). Maximum plasma conc. for the initial oral 400 mg loading dose was typically achieved with a mean value of approximately 4 hours. Maximum plasma conc. for a 200 mg dose was also achieved with a mean value of about 4 hours. Oral absorption of Sparfloxacin is unaffected by administration of food, milk or any high fat meals.
Distribution: Upon reaching general circulation, Sparfloxacin distributes well into the body. Sparfloxacin exhibits low plasma protein binding in serum at about 45%.
Metabolism: Its' metabolism does not interfere with cytochrome-mediated oxidation, in particular cytochrome P-450.
Excretion: The elimination-half life ($t_{1/2}$) of Sparfloxacin in plasma generally varies between 16 and 30 hours, with a mean ($t_{1/2}$) of approximately 20 hours.

Pharmacodynamics:
Mechanism of action: Sparfloxacin exerts its antibacterial activity by inhibiting DNA gyrase. DNA gyrase is an enzyme responsible for DNA replication, repair, deactivation and transcription.

Microbiology:
Sparfloxacin has invitro activity against a wide range of gram-negative and garm-positive micro organisms.
Some of the major micro-organisms are as follows:
Gram positive micro-organisms
Staphylococcus aureus
Streptococcus pneumoniae
Gram negative micro organisms
Haemophilus influenzae
Klebsiella pneumoniae
Moraxella catarrhalis
Other micro-organisms
Chlamydia pneumoniae
Mycoplasma pneumoniae

Indication:
Saga™ is indicated for the treatment of adults (>18 years of age) with the following upper and lower respiratory tract infections caused by susceptible strains of microorganisms:

- Sinusitis
- Community and hospital acquired pneumonia
- Bronchitis
- Acute Bacterial Exacerbation of Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease (COPD)
- Lungs abscess
- All other RTIs

Besides, **Saga**™ can also be indicated in-

- Urinary Tract Infection including gonococcal and non-gonococcal urethritis, chancroid and other STD's
- Skin and Soft Tissue Infections

Dosage and Administration:
In patients with normal renal function the recommended daily dose is two tablets of **Saga**™ on first day as a loading dose, thereafter one tablet of **Saga**™ tablet is to be taken every 24 hours for a total of 10 days of therapy (11 tablets). The recommended daily dose of **Saga**™ in patients with renal impairment (Creatinine clearance < 50 ml/min) is two tablets of 200 mg taken on the first day as a loading dose. Thereafter, one tablet of 200 mg should be taken every 48 hours for total of 9 days of therapy (6 tablets). **Saga**™can be taken with or without food.

Contraindication:
Sparfloxacin is contraindicated for individuals with a history of hypersensitivity and in achilles tendinits following the use of fluoroquinolone and in pregnancy and lactation. Sparfloxacin is contraindicated in patients with known QT_C prolongation or in patients being treated concomitantly with medications known to produce an increase in the QT_C interval and/or torsade depointes.

Precautions and Warning:
Adjustment of the dosage regimen is necessary for the patients with impaired renal function (creatinine clearance < 50 ml / min).

Side Effect:
Most of the adverse events were mild to moderate in severity and transient in nature. The most frequently reported events among the Sparfloxacin treated patients with the recommended dosage are: diarrhea, nausea, headache, dyspepsia, dizziness, insomnia, abdominal pain and QT_C interval prolongation.

Drug Interaction:
Antacids and Sucralfate: Aluminium and magnesium cations in antacids and sucralfate form chelation complexes with Sparfloxacin. Oral bioavailabilily of sparfloxacin is not hampered if antacids/ sucralfale is administered four hours following sparfloxacin administration.
Zinc/iron salts: Absorption of quinolones is reduced significantly by these preparations.

Adverse Drug Reaction:
Risk of Retinal detachment.

Use in Pregnancy and Lactation:
There are no adequate and well controlled studies in pregnant women. Sparfloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Paediatric use:
Safety and effectiveness have not been established in patients below the age of 18 years.

Storage Condition:
Keep protected from light and moisture. Store below 30° C. Keep out the reach of children.

How Supplied:
Saga™ Tablet : Box containing 3 x 5 tablets in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH