



Saga[®]
Sparfloxacin
Fluoroquinolone

COMPOSITION

Saga[®] 200 Tablet: Each film coated tablet contains sparfloxacin INN 200 mg.

PHARMACOLOGY

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 gram-positive micro organisms.

Aerobic gram negative micro organisms

Enterobacter cloacae

Haemophilus influenzae

Haemophilus parainfluenzae

Klebsiella pneumoniae

Moraxella catarrhalis

Other micro-organisms

Chlamydia pneumoniae

Mycoplasma pneumoniae

Aerobic gram positive micro-organisms

Streptococcus agalactiae

Streptococcus aureus

Streptococcus pneumoniae (penicillin susceptible strains)

Streptococcus pyogenes

Viridans group of streptococci

Aerobic gram negative micro-organisms

Acinetobacter anitratus

Acinetobacter lwoffii

Citrobacter diversis

Enterobacter aerogenes

Klebsiella oxytoca

Legionella pneumophila

Morganiella morgani

Proteus mirabili

Proteus vulgaris

QUINOLONE & FLUROQUINOLONE ANTIBIOTICS

INDICATION

Sparfloxacin is indicated for the treatment of adults (≥ 18 years of age) with the following infections caused by susceptible strains of the designated microorganisms:

Community acquired pneumonia caused by *Chlamydia pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Moraxella catarrhalis*, *Mycoplasma pneumoniae* or *Streptococcus pneumoniae*.

Acute Bacterial Exacerbation of Chronic Bronchitis caused by *Chlamydia pneumoniae*, *Enterobacter cloacae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Staphylococcus aureus* or *Streptococcus pneumoniae*.

DOSAGE AND ADMINISTRATION

In patients with normal renal function the recommended daily dose is two tablets of Saga® 200 mg on first day as a loading dose, thereafter take one tablet of Saga® 200 mg every 24 hours for a total of 10 days of therapy.

The recommended daily dose of Saga® in patients with renal impairment (Creatinine clearance < 30 ml/min) is two tablets of 200 mg taken on the first day as a loading dose. Thereafter, should be taken one tablet of 200 mg every 48 hours for total of 9 days of therapy.

Saga® can be taken with or without food.

CONTRAINDICATION AND PRECAUTION

Sparfloxacin is contraindicated for individuals with a history of hypersensitivity or photosensitivity reactions. Sparfloxacin is contraindicated in patients with known prolongation or in patients being treated concomitantly with medications known to produce an increase in the QTc interval and/or torsade de pointes.

Moderate to severe phototoxic reactions have occurred in patients exposed to direct or indirect sunlight or to artificial ultraviolet light (e.g. sunlamps) during or following treatment. Patients should be advised to discontinue sparfloxacin therapy at the first signs or symptoms of a phototoxicity reaction such as a sensation of skin burning, redness, swelling, blisters, rash, itching or dermatitis.

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: Photosensitivity reaction, diarrhoea, nausea, headache, dyspepsia, dizziness, insomnia, abdominal pain and QTc interval prolongation.

DRUG INTERACTION

Antacids and Sucralfate: Aluminium and magnesium cations in antacids and sucralfate form chelation complexes with Sparfloxacin.

Zinc/iron salts: Absorption of quinolones is reduced significantly by these preparations.

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.

USE IN PAEDIATRICS

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

STORAGE CONDITION

Store at temperature below 30°C.

HOW SUPPLIED

Saga® 200 tablet : Each box contains 2 x 5 film coated tablet in blister pack.

