

کیوسپار®
سپارفلوکسائین ۱۰۰ ملیگرام
وسع النمل ایشی پائیونٹ

PAG
E
1/2

QuSpar®
Sparfloxacin
100 mg Broad Spectrum Antibiotic

COMPOSITION: Each film coated tablet contains:
 Sparfloxacin 100 mg

CLINICAL PHARMACOLOGY:
 Sparfloxacin is a long acting quinolone anti-bacterial agent. It is a broad spectrum DNA-gyrase inhibitor, a fourth generation fluoroquinolone derivative having strong bactericidal activity against variety of multi-resistant gram-positive and gram-negative pathogens, glucose, non-fermenters, anaerobes and chlamydia species. It exerts more potent bactericidal effect especially against gram-positive and chlamydia species compared with existing new quinolones. It exerts its anti-bacterial activity via the inhibition of DNA replication of bacteria by inhibiting DNA gyrase activity. DNA gyrase is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA.

ANTI-MICROBIAL ACTIVITY:
 Anti-microbial activity of sparfloxacin is 2 to 32 times stronger than ciprofloxacin, ofloxacin and enoxacin against gram-negative organisms and anaerobes while stronger than erythromycin and ofloxacin and equal to minocycline against chlamydia trachomatis. It has more potent anti-bacterial activity than ciprofloxacin, ofloxacin, enoxacin and norfloxacin against gram-positive organisms such as *S. pneumoniae*, *S. pyogenes*, *Staphylococcus* sp., *Enterococcus* sp., anaerobes and chlamydia trachomatis. Sparfloxacin is effective against the following micro-organisms: *S. pneumoniae*, *S. pyogenes*, *Staphylococcus* sp., *Haemolytic streptococcus*, *Neisseria gonorrhoeae*, *Branhamella catarrhalis*, *Escherichia coli*, *Citrobacter* sp., *Salmonella* sp., (including *S. typhi* and *S. paratyphi*), *Shigella* sp., *Klebsiella* sp., *Enterobacter* sp., *Serratia* sp., *Proteus* sp., *Morganella morganii*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Acinetobacter* sp., *Peptostreptococcus* sp., *Propionibacterium acnes*, *Bacteroides* sp., *Chlamydia trachomatis* and mycobacterium tuberculosis.

Indications and Usage:
 QuSpar is used for the treatment of community-acquired pneumonia and acute bacterial exacerbations of chronic bronchitis including those caused by pneumococci. It is indicated in acute, chronic and recurrent infections caused by the susceptible strains of micro-organisms in the following pathological conditions:

Respiratory tract infections: pneumonia, pharyngitis, tonsillitis, acute bronchitis, chronic bronchitis, bronchiectasis with exacerbations and secondary infections of chronic respiratory disease.

Otorhinolaryngological infections: ¹¹ otitis media, sinusitis

Urinary tract infections: uterine adhesions, intrauterine infection, cervicitis, Bartholinitis.

Skin and soft tissue infections: acne pustulosa, acne conglobata, folliculitis, furunculosis, carbuncle, impetigo, ecthyma, cellulitis, abscess, lymphangitis, lymphadenitis.

Manufacture:
Schazzoo Zaka (Pvt) Ltd.
 Kalawala, 20 Km Lahore-Jaranwala
 Road,
 Distt: Sheikhupura, Pakistan.

Ed
ed
by

R&D	R&D	R&D	R&D
OFFICE	MANAGE	MANAGE	MANAGE
R	R	R	R
2/2/2	2/2/2	2/2/2	2/2/2

Colour Key
Black
ze
:
W:
18
O
H:
14
O

Leaflet:
Flying Paper
55 gm

Gynaecological infections --Pyelonephritis, cystitis, prostatitis, gonococcal urethritis and non gonococcal urethritis.
Surgical infections--Mastitis, perirectal abscess, secondary superficial infections after wounds, burns and surgical incisions etc.
Multi-drug resistant TB patients-- Recent use of Sparfloxacin along with other anti-tuberculosis drugs appears to be effective and safe for MDR-TB patients.

DOSAGE AND ADMINISTRATION:
Adults: For the treatment of infection, oral administration of 400mg on the first day then 200mg once daily for nine days, or as advised by the physician.
For MDR-TB patients: Initial dose is 400mg once daily which is reduced to 200mg once daily. Duration of treatment for MDR-TB patients is 2.5-4 months.
Children below 18 years of age: As advised by the physician.

CONTRA-INDICATIONS:
 Sparfloxacin is contra-indicated for individuals with a history of hypersensitivity phototoxicity reactions. Consequently it is contra-indicated for individuals receiving disopyramide and amiodarone as well as other QTc prolonging antiarrhythmic drugs reported to cause torsade de pointes, such as quinidine, procainamide, sotalol and dofetilide.

PRECAUTIONS AND WARNINGS:
 . 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. These reactions have also occurred in patients exposed to shaded or diffuse light, including exposure through glass or shaded or during cloudy weather. Patients should be advised to discontinue sparfloxacin therapy at the first signs or symptoms of phototoxicity reaction such as sensation of skin burning, redness, swelling, blisters, rash, itching, or dermatitis.
 Adequate hydration of patients receiving sparfloxacin should be maintained to prevent the formation of a highly concentrated urine.
 As with other quinolones, sparfloxacin should be used with caution in any patient with a known or suspected CNS disorder that may predispose to seizure.
 Sparfloxacin should be administered with caution to the patients with renal insufficiency. Dosage adjustment is necessary for those patients whose renal creatinine clearance is 50ml/min.

DRUG INTERACTIONS:
Digoxin: Sparfloxacin has no effect on the pharmacokinetics of digoxin.

Methylenethiones: Sparfloxacin does not increase plasma by theophylline concentrations. Since there is no interaction with theophylline, interaction with other methylenethiones such as caffeine is unlikely.

Warfarin: Sparfloxacin does not increase the anti-coagulant effect of warfarin.

Cimetidine: Cimetidine does not effect the pharmacokinetics of sparfloxacin.

Antacids and sucralfate: Aluminium and magnesium cations in antacids and sucralfate form chelation complexes with sparfloxacin. The oral bioavailability of sparfloxacin is reduced

Colour Key
Black
ze
:
W:
18
O
H:
14
O

Leaflet:
Flying Paper
55 gm

PAG
E
2/2

the importance of the drug to the mother.
PEDIATRIC USE:
 Safety and effectiveness in pediatric patients below 18 years have not been established.
GERIATRIC USE:
 Pharmacokinetics of sparfloxacin are not altered in elderly with normal renal function.

SIDE EFFECTS:
Body as a whole-- Fever, chest pain, generalized pain, allergic reactions, cellulitis, back pain, chills, face edema, malaise, accidental injury, anaphylactic reaction, infection, mucus membrane disorder, neck pain and rheumatoid arthritis.
GIT disturbances-- Constipation, anorexia, gingivitis, oral moniliasis, stomatitis, tongue disorder, tooth disorder, gastroenteritis, increased appetite, mouth ulceration, vomiting and flatulence.
CNS disturbances-- Euphoria, abnormal thinking, amnesia, twitching, tremor, anxiety, vertigo, abnormal dreams, confusion, agitation, abnormal gait and hallucinations.
CVS disturbances-- Palpitation, electrocardiogram abnormality, hypertension, tachycardia, sinus bradycardia, migraine, peripheral vascular disorder and atrial flutter etc.
Hematologic: Cyanosis, ecchymosis and lymphadenopathy.
Metabolism: Gout, peripheral edema and thirst.
Musculoskeletal: Arthralgia, arthritis and myalgia.
Respiratory disorder: Asthma, epistaxis, pneumonia, rhinitis, pharyngitis, bronchitis, hemoptysis, increased cough and dyspnoea etc.
Skin disorders-- rash, dry skin, sweating, urticaria, acne, alopecia, angioedema, contact dermatitis and skin discoloration.
Special sense disturbances-- ear and eye pain, amblyopia, photophobia, tinnitus, diplopia, conjunctivitis, diplopia, lacrimation disorder and otitis media etc.
Urogenital: Vaginitis, dysuria, breast pain, dysmenorrhea, hematuria, urinary tract infection and nocturia etc.

OVERDOSEAGE:
 The patient should be monitored in a suitably equipped medical facility and advised to avoid sun exposure for five days. ECG monitoring is recommended due to the possible prolongation of the QTc interval. There is no known antidote for sparfloxacin over dosage.

INFORMATIONS FOR PATIENTS:	
Patients should be advised:	
i)	to avoid exposure to direct or indirect sunlight, artificial ultraviolet light during the treatment with sparfloxacin and for 5 days after therapy
ii)	to discontinue sparfloxacin therapy at the first sign or symptom of phototoxicity
iii)	to discontinue sparfloxacin therapy and inform physician if reaction such as redness, swelling, blisters, itching, rash or dermatitis, pain, inflammation or rupture of tendon occur.
iv)	to take mineral supplements of vitamins with iron, zinc, calcium 4 hours after sparfloxacin administration.
v)	to drink fluids frequently.
vi)	to take sucralfate or magnesium and aluminium-containing antacids 4 hours after sparfloxacin administration.