The manufacturer only recommends use of sparfloxacin during pregnancy when benefit outweighs risk of 549 cases reported by the European Network of Teratology Information Services involving exposure to other fluoroquinolones, congenital malformations were reported in 4.8%; however, this was not higher than the background rate.

Breast-feeding

Sparfloxacin is excreted into human milk. Cartilage erosion and arthropathy have been reported in immature animals giving rise to concern over toxic effects in the developing joints of nursing infants. The manufacturer recommends that due to the potential for serious adverse reactions in nursing infants, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

1.3.1.6.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Patients should be warned about the potential for central nervous system effects, and advised not to drive or operate machinery whilst taking sparfloxacin.

1.3.1.6.8 UNDESIRABLE EFFECTS

Photo toxicity including manifestations of sunburn, erythema and severe bullous lesions. Recurrence of the symptoms after a new sun exposure, several weeks after the end of the treatment, has been sometimes observed.

Skin reactions: rash, pruritus, swelling, blisters.

Musculoskeletal: muscle or joint pain, tendinitis, ruptured tendon.

Cardiovascular: rare cardiac rhythm disorders including torsades de pointes, arrhythmia, bradycardia, tachycardia and ventricular tachycardia.

Digestive disorders: nausea, vomiting, diarrhoea, abdominal pain, gastralgia.

Nervous System: tremor, feeling drunk, paraesthesia, sensory disturbance, headache and vertigo.

Psychiatric disorders: hallucinations, sleep disorders at the beginning of treatment.