For the use only of a Registered Medical Practitioners

℞ Satranidazole And Ofloxacin For Oral Suspension

SATROGYL®-O DRY SYRUP

सैट्रोजिल-ओ ड्राय सिरप

1. NAME OF THE MEDICINAL PRODUCT
Satranidazole And Ofloxacin For Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5 ml of reconstituted suspension contains:
Satranidazole.....75 mg
Ofloxacin IP.....50 mg
Excipients.....q.s.
Colour: Quinoline Yellow WS.

3. PHARMACEUTICAL FORM
Dry syrup

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
Satrogyl-O dry syrup is indicated for the treatment of diarrhoea of mixed infection in adults

4.2 Posology and Method of Administration (Adult)
Syrup:
20ml of Satrogyl-O twice daily or as directed by physician

4.3 Contraindications
Ofloxacin:
Ofloxacin should not be used in patients with known hypersensitivity to 4-quinolone antibacterials or any of the tablet excipients. Ofloxacin should not be used in patients with a past history of tendinitis. Ofloxacin, like other 4-quinolones, is contra-indicated in patients with a history of epilepsy or with a lowered seizure threshold. In children or growing adolescents, and in pregnant or breastfeeding women, since animal experiments do not entirely exclude the risk of damage to the growth-plate cartilage in the growing organism cannot be entirely excluded. Patients with latent or actual defects in glucose-6-phosphate dehydrogenese activity may be prone to haemolytic reactions when treated with quinolone antibacterial agents.
Satranidazole:
Any hypersensitivity to Satranidazole or Nitroimidazoles drugs. As with other drugs of similar structure, Satranidazole is contraindicated in patients having, or with a history of, blood dyscrasia, although no haematological abnormalities have been noted in clinical or animal studies. Satranidazole should be avoided in patients with organic neurological disorders in view of the other drugs of similar structure causing neurological disorders.

4.4 Special Warnings and Special Precautions for Use
Ofloxacin:

WARNING: Fluoroquinolones, including Ofloxacin, are associated with an increased risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients usually over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants. Fluoroquinolones, including Ofloxacin, may exacerbate muscle weakness in persons with myasthenia gravis. Avoid Ofloxacin in patients with a known history of myasthenia gravis.

"The drug may cause low blood sugar and mental health related side effects. Low blood sugar levels, also called hypoglycaemia, can lead to coma. The mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class. The mental health side effects to be added to or updated across all the fluoroquinolones are:
o disturbances in attention
o disorientation
o agitation
o nervousness
o memory impairment
o Serious disturbances in mental abilities called delirium."
Hypersensitivity and allergic reactions including Anaphylactic and anaphylactoid reactions have been reported for fluoroquinolones. In these cases ofloxacin should be discontinued and suitable treatment (e,g treatment for shock) should be initiated. Clostridium difficile-associated disease Diarrhoea, pseudo-membranous colitis have been reported with treatment with Ofloxacin, if suspected, ofloxacin must be stopped immediately. Appropriate specific antibiotic therapy must be started without delay (e.g, oral vancomycin, oral teicoplanin or metronidazole). Products inhibiting the peristalsis are contraindicated in this clinical situation
Patients predisposed to seizures In case of convulsive seizures, treatment with ofloxacin should be discontinued. Very rare cases of QT interval prolongation have been reported in patients taking fluoroquinolones. Caution should be taken when using fluoroquinolones, including ofloxacin, in patients with known risk factors for prolongation of the QT interval such as, for example congenital long QT syndrome, concomitant use of drugs that are known to prolong the QT interval (e.g, Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics), uncorrected electrolyte imbalance (e.g. hypokalaemia, hypomagnesaemia), cardiac disease (e,g, heart failure, myocardial infarction, bradycardia). Elderly patients and women may be more sensitive to QTc-prolonging medications. Therefore, caution should be taken when using fluoroquinolones, including Ofloxacin, in these populations. Patients being treated with ofloxacin and should avoid strong sunlight and UV rays (sun lamps, solaria). Patients with history of psychotic disorder, Psychotic reactions have been reported in patients receiving fluoroquinolones. In the event that a patient develops these reactions, ofloxacin should be discontinued and appropriate measures instituted. Ofloxacin should be used with caution in patients with a history of psychotic disorder or in patients with psychiatric disease. Patients with impaired liver function Ofloxacin should be used with caution in patients with impaired liver function, as liver damage may occur. Cases of fulminant hepatitis potentially leading to liver failure (including fatal cases) have been reported with fluoroquinolones. Patients should be advised to stop treatment and contact their doctor if signs and symptoms of hepatic disease develop such as anorexia, jaundice, dark urine, pruritis or tender abdomen. (See section 4.8: Undesirable effects) Due to possible increase in coagulation tests (PT/INR) and/or bleeding in patients treated with fluoroquinolones, including ofloxacin, in combination with a vitamin K antagonist (e.g.warfarin), coagulation tests should be monitored when these drugs are given concomitantly (see section 4.5) Ofloxacin should be used with caution in patients with a history of myasthenia gravis.
Administration of antibiotics, especially of prolonged, may lead to proliferation of resistant micro-organisms. The patient's condition must therefore be checked at regular intervals. If a secondary infection occurs, appropriate measures must be taken, Sensory or sensorimotor peripheral neuropathy has been reported in patients receiving fluoroquinolones, including ofloxacin. Ofloxacin should be discontinued if the patient experiences symptoms of neuropathy in order to prevent the development of an irreversible condition. As with all quinolones, hypoglycaemia has been reported, usually in diabetic patients receiving concomitant treatment with an oral hypoglycaemic agent (e.g. glibenclamide) or with insulin. In these diabetic patients, careful monitoring of blood glucose is recommended. Patients with latent or diagnosed glucose-6-phosphate-dehydrogenase deficiency may be predisposed to haemolytic reactions if they are treated with quinolones. Ofloxacin should therefore be administered with caution in such patients. Patients with rare hereditary disorders of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Satranidazole:
Satranidazole was well tolerated by animals and had excellent CNS tolerability. However, drugs of similar chemical structure have produced various neurological disturbances such as dizziness, vertigo, incoordination and ataxia. If during therapy abnormal neurological signs develop, therapy should be discontinued. Carcinogenicity has been seen in mice and rats treated chronically with metronidazole, another nitroimidazole agent. Although carcinogenicity data is not available for Satrandidazole, the two drugs are structurally related and therefore there is a potential for similar biologic effects. The use of Satanidazole for longer treatment than usually required should be carefully considered. As with related compounds, alcoholic beverages should be avoided during Satranidazole therapy because of the possibility of a disulfiram-like reaction (flushing, abdominal cramps, vomiting, tachycardia). Alcohol should be avoided until 72 hours after discontinuing Satrogyl-O.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction
Ofloxacin:
Co-administered magnesium/aluminium antacids, sucralfate, zinc or iron preparations can reduce absorption. Therefore, ofloxacin should be taken 2 hours before such preparations. Prolongation of bleeding time has been reported during concomitant administration of ofloxacin and anticoagulants. There may be a further lowering of the cerebral seizure threshold when quinolones are given concurrently with other drugs which lower the seizure threshold, e.g. theophylline. However ofloxacin is not thought to cause a pharmacokinetic interaction with theophylline, unlike some other fluoroquinolones. Further lowering of the cerebral seizure threshold may also occur with certain nonsteroidal anti-inflammatory drugs. In case of convulsive seizures, treatment with ofloxacin should be discontinued. Ofloxacin may cause a slight increase in serum concentrations of glibenclamide administered concurrently; patients treated with this combination should be closely monitored. With high doses of quinolones, impairment of excretion and an increase in serum levels may occur when co-administered with other drugs that undergo renal tubular secretion (e.g. probenecid, cimetidine, frusemide and methotrexate). Interaction with laboratory tests: Determination of opiates or porphyrins in urine may give false-positive results during treatment with ofloxacin. It may be necessary to confirm positive opiate or porphyrin screens by more specific methods. Vitamin K antagonists Coagulation tests should be monitored in patients treated with vitamin K antagonists because of a possible increase in the effect of coumarin derivatives.
Satranidazole:
Drugs of similar chemical structure have been shown to potentiate the effects of oral anticoagulants. Prothrombin time should be closely monitored and adjustments to the dose of the anticoagulants should be made as necessary. Concurrent use of Satranidazole and alcohol may produce a disulfiram-like reaction and should be avoided.

4.6 Fertility, Pregnancy and Lactation
Ofloxacin:
Based on a limited amount of human data, the use of fluoroquinolones in the first trimester of pregnancy has not been associated with an increased risk of major malformations or other adverse effects on pregnancy outcome. Animal studies have shown damage to the joint cartilage in immature animals but no teratogenic effects. Therefore, ofloxacin should not be used during pregnancy. Ofloxacin is excreted into human breast milk in small amounts. Because of the potential for arthropathy and other serious toxicity in the nursing infant, breast feeding should be discontinued during treatment with ofloxacin.
Satranidazole:
Satranidazole was neither embryotoxic nor teratogenic to the rat-foetuses, when the mothers were medicated at the Satranidazole doses 0, 100, 300 and 600 mg/kg during their critical phase of the pregnancy. Human studies on this aspect are lacking.
• It is not known It is not known whether satranidazole is excreted in human milk following oral administration. Per oral LD0 in neonatal rat was >3000 mg/kg and in weaning rat >5000 mg/kg.

4.7 Effects on Ability to Drive and Use Machines
Ofloxacin
Since there have been occasional reports of somnolence, impairment of skills, dizziness and visual disturbances, patients should know how they react to ofloxacin before they drive or operate machinery. These effects may be enhanced by alcohol.
Satranidazole:
No special precautions should be necessary.

System organ class	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Very rare (< 1/10,000)	Not known (cannot be estimated from available data)*
Infections and infestations		Fungal infection, Pathogen resistance			
Blood and the lymphatic system disorders				Anaemia Haemolytic anaemia, Leukopenia, Eosinophilia, Thrombocytopenia	Agranulocytosis Bone marrow failure
Immune system disorders			Anaphylactic reaction*, Anaphylactoid reaction*, Angioedema*	Anaphylactic shock*, Anaphylactoid shock*	
Metabolism and Nutrition disorders			Anorexia		Hypoglycaemia in diabetics treated with hypoglycaemic agents (see Section 4.4)
Psychiatric disorders		Agitation, Sleep disorder, Insomnia	Psychotic disorder (for e.g. hallucination), Anxiety, Confusional state, Nightmares, Depression		Psychotic disorder and depression with self-endangering behaviour including suicidal ideation or suicide attempt (see Section 4.4)
Nervous system disorders		Dizziness, Headache	Somnolence, Paraesthesia, Dysgeusia, Parosmia	Peripheral sensory neuropathy* Peripheral sensory motor neuropathy* Convulsion*, Extra-pyramidial symptoms or other disorders of muscular coordination	
Eye disorders		Eye irritation	Visual disturbance		
Ear and labyrinth disorders		Vertigo		Tinnitus, Hearing loss	
Cardiac disorders			Tachycardia		Ventricular arrhythmias, torsades de pointes (reported predominantly in patients with risk factors for QT prolongation), ECG QT prolonged (see section 4.4 and 4.9)
Vascular disorders	applies only to the solution for infusion: Phlebitis		Hypotension		applies only to the solution for infusion: During infusion of ofloxacin, tachycardia and hypotension may occur. Such a decrease in blood pressure may, in very rare cases, be severe.
Respiratory, thoracic and mediastinal disorders		Cough, Naso-pharyngitis	Dyspnoea, Bronchospasm		Allergic pneumonitis, Severe dyspnoea
Gastrointestinal disorders		Abdominal pain, Diarrhoea, Nausea, Vomiting	Enterocolitis, sometimes haemorrhagic	Pseudo-membranous colitis*	
Hepatobiliary disorders			Hepatic enzymes increased (ALAT, ASAT, LDH, gamma-GT and/or alkaline phosphatase) Blood bilirubin increased	Jaundice cholestatic	Hepatitis, which may be severe*
Skin and subcutaneous tissue disorders		Pruritus, Rash	Urticaria, Hot flushes, Hyperhidrosis Pustular rash	Erythema multiforme, Toxic epidermal necrolysis, Photo-sensitivity reaction*, Drug eruption Vascular purpura, Vasculitis, which can lead in exceptional cases to skin necrosis	Stevens-Johnson syndrome; Acute generalized exanthemous pustulosis; drug rash
Musculoskeletal and Connective tissue disorders			Tendonitis	Arthralgia, Myalgia, Tendon rupture (e.g. Achilles tendon) which may occur within 48 hours of treatment start and may be bilateral,	Rhabdomyolysis and/or Myopathy, Muscular weakness Muscle tear, muscle rupture
Renal and Urinary disorders			Serum creatinine increased	Acute renal failure	Acute interstitial nephritis
Congenital and familial/ genetic disorders					Attacks of porphyria in patients with porphyria
General disorders and administration site conditions	applies only to the solution for infusion: Infusion site reaction , (pain, reddening)				

*Postmarketing experience

Satranidazole:
Reported side effects have generally been infrequent, mild and self-limiting. The reported undesirable effects include allergy, nausea, vomiting & acidity, metallic taste.

4.9 Overdose
Ofloxacin:
The most important signs to be expected following acute overdosage are CNS symptoms such as confusion, dizziness, impairment of consciousness and convulsive seizures as well as gastrointestinal reactions such as nausea and mucosal erosions. In the case of overdose steps to remove any unabsorbed ofloxacin eg, gastric lavage, administration of adsorb ants and sodium sulphate, if possible during the first 30 minutes, are recommended; antacids are recommended for protection of the gastric mucosa. Elimination of ofloxacin may be increased by forced diuresis. In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.
Satranidazole:
• In acute animal studies, an oral dose of 5000 mg/kg to mouse, rat, rabbit and guineapig and 3000 mg/kg to dog was tolerated without exhibiting any toxic effects. Per oral LD0 in mouse was >5000 mg/kg, in neonatal rat was >3000 mg/kg, in weaning rat >5000 mg/kg, in geriatric rat >5000 mg/kg, in rabbit >5000 mg/kg and in dog was > 3000 mg/kg. When given intra-peritoneally, LD0 in rat >200 mg/kg and in dog was >500 mg/kg. Signs and symptoms of overdosage: There are no reported overdoses in humans with Satranidazole. Treatment for overdosage: There is no specific antidote for treatment of overdosage with Satranidazole. Treatment is symptomatic and supportive. Gastric lavage may be useful.

5. PHARMACOLOGICAL PROPERTIES
5.1 Mechanism of Action
Satranidazole produces extensive DNA breakage characterized by strand breakage and helix destabilization. 5-nitroimidazoles indicate it may be more potent towards anaerobes other 5-nitroimidazoles because its high redox potential are more resistant to inactivation by oxygen. Ofloxacin inhibits bacterial DNA replication by blocking DNA topoisomerases, in particular DNA gyrase.

5.2 Pharmacodynamic Properties
Pharmacotherapeutic group: Quinolone antibacterials, Fluoroquinolones. ATC code J01M A01 Ofloxacin is a quinolone-carboxylic acid derivative with a wide range of antibacterial activity against both gram negative and gram positive organisms. It is active after oral administration. It inhibits bacterial DNA replication by blocking DNA topoisomerases, in particular DNA gyrase. Therapeutic doses of ofloxacin are devoid of pharmacological effects on the voluntary or autonomic nervous systems. Microbiological results indicate that the following pathogens may be regarded as sensitive: Staphylococcus aureus (including methicillin resistant staphylococci). Staphylococcus epidermidis, Neisseria species, Escherichia coli, Citrobacter, Klebsiella, Enterobacter, Hafnia, Proteus (indole-negative and indole-positive strains), Haemophilus influenzae, Chlamydiae, Legionella, Gardnerella. Variable sensitivity is shown by Streptococci, Serratia marcescens, Pseudomonas aeruginosa and Mycoplasmas. Anaerobic bacteria (e,g, Fusobacterium species, Bacteroides species, Eubacterium species, Peptococci, Peptostreptococci) are normally resistant.
Satranidazole:
Satranidazole (CG-10213-Go), a novel nitroimidazole possessing a C-N linkage at C2 of the imidazole ring has been examined, during reduction, for its ability to damage DNA. Physical damage to DNA was measured by viscometry, thermal denaturation and renaturation, and hydroxyapatite chromatography. Biologically relevant DNA damage was measured by a bacteriophage transfection assay. The drug produces extensive DNA damage characterized by helix destabilization and strand breakage. Its comparison with other 2- and 5-nitroimidazoles indicate it may be more active towards anaerobes than many 5-nitroimidazoles because its relatively high redox potential may make it more resistant to inactivation by oxygen. The in-vivo amoebicidal activity of satranidazole and metronidazole compounds was evaluated in the acute hamster hepatic model of amoebiasis. Both metronidazole and satranidazole were administered as single graded doses po, and their dose-response profiles were characterized. Satranidazole demonstrated significantly greater amoebicidal activity than metronidazole with an ED50 value of 19,5 mg/kg, compared to an ED50 value of 45 mg/kg for metronidazole. These data suggest that higher plasma and liver concentrations of satranidazole and greater intrinsic potency probably contribute to superior amoebicidal activity in the hamster model of hepatic infection.

5.3 Pharmacokinetic Properties
Ofloxacin:
Ofloxacin is almost completely absorbed after oral administration. Maximal blood levels occur 1-3 hours after dosing and the elimination half-life is 4-6 hours. Ofloxacin is primarily excreted unchanged in the urine. In renal insufficiency the dose should be reduced. No clinically relevant interactions were seen with food and no interaction was found between ofloxacin and theophylline.
Satranidazole:
Pharmacokinetic studies of satranidazole in humans have demonstrated a longer half-life (satranidazole 14 hours; metronidazole 8 hours) and higher blood levels than metronidazole. These factors combined with its greater potency are believed to contribute to its therapeutic efficacy. Comparative pharmacokinetics in animal study: The pharmacokinetic properties of metronidazole and satranidazole were studied in the golden hamster (Mesocricetus auratus). at a dose of 80 mg/kg po. Satranidazole exhibited significantly higher plasma concentrations than metronidazole at 1 and 2 h post-dose, but the comparative Cmax values were not significantly different. The satranidazole plasma elimination half-life of 1,01 h was significantly shorter than the corresponding metronidazole half-life of 3-62 h. The comparative liver pharmacokinetic parameters Cmax, Tmax and t½ did not differ significantly.

5.4 Preclinical Safety Data
Ofloxacin:
Preclinical effects in conventional studies of safety pharmacology, acute toxicity, repeated dose toxicity, reproductive studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use. Joint toxicity was observed at exposure in the human therapeutic range in juvenile rats and dogs. Ofloxacin exhibits a neurotoxic potential and causes reversible testicular alterations at high doses.
Satranidazole:
Satranidazole delineates its absence of central and peripheral neurotoxicity when administered in moderately high doses to different animal species. Whereas Metronidazole induced neurotoxicity. Satranidazole compares favourably with Metronidazole in animal tests for cardiovascular tolerability. Satranidazole appears to be neither embryotoxic nor teratogenic to the rat-foetuses, when the mothers were medicated at the aforesaid doses, during their critical phase of the pregnancy.

6. Nonclinical Properties:
6.1 Animal Toxicology or Pharmacology
Preclinical effects in conventional studies of safety pharmacology, acute toxicity, repeated dose toxicity, reproductive studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use. Joint toxicity was observed at exposure in the human therapeutic range in juvenile rats and dogs. Ofloxacin exhibits a neurotoxic potential and causes reversible testicular alterations at high doses. Mutagenicity studies showed no evidence for mutagenicity of ofloxacin. However, like some other quinolones Ofloxacin is phototoxic in animals at exposure in the human therapeutic range. The phototoxic, photomutagenic and photocarcinogenic potential of ofloxacin is comparable with that of other gyrase inhibitors. Preclinical data from conventional genotoxicity studies reveal no special hazard to humans, carcinogen potential has not been investigated.
Reproduction toxicity
Ofloxacin has no effect on fertility, peri- or postnatal development, and therapeutic doses did not lead to any teratogenic or other embryotoxic effects in animals. Ofloxacin crosses the placenta and levels reached in the amniotic fluid are about 30% of the maximal concentrations measured in maternal serum.
Satranidazole:
An oral dose of 5000 mg/kg to mouse, rat, rabbit and guineapig and 3000 mg/kg to dog was tolerated without exhibiting any toxic effects. The dog on 5000 mg/kg exhibited spasticity muscular tremors, ataxia, stupor, coma and death. It was found dead on day 3. No drug induced toxic symptoms were noticed in rats treated with 200 mg/kg and dog 500 mg/kg given i.p.

7. Description:
Yellow granular powder.
On reconstitution-Yellow colour suspension having vanilla flavour.

8. Pharmaceutical particulars:
30 ml & 60 ml in HDPE bottle.

8.1 Incompatibilities
Not applicable

8.2 Shelf-life
24 months.

8.3 Packaging Information:
30 ml & 60 ml in HDPE bottle.

8.4 Storage and handling instructions:
Store in a cool dry place, protected from light at a temperature not exceeding 30°C.

9 Patient Counselling Information
Do not take this medication:
• if you are allergic to Ofloxacin or Satranidazole any of the other ingredients of this medicine. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
• Do not take this if you have previously had an allergic reaction to another quinolone antibiotic e.g. ciprofloxacin or norfloxacin.
• If you suffer from epilepsy or are at risk of fits.
• If you have a history of inflammation and swelling of the tendons (tendonitis) which can affect areas such as the wrist or the achilles tendon after treatment with a quinolone antibiotic e.g. ciprofloxacin, norfloxacin, or nadifloxacin.
• If you suffer from or there is a family history of glucose-6-phosphate dehydrogenase deficiency (an inherited disorder that affects the red blood cells)
• If you are pregnant, think you may be pregnant or are planning to have a baby.
• If you are breastfeeding.
• If you are under the age of 18 years, or are still growing.
Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Ofloxacin.

Warnings and precautions
Before taking this medicine
You should not take fluoroquinolone/quinolone antibacterial medicines, including Ofloxacin, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.
Talk to your doctor or pharmacist before taking Ofloxacin if any of the following apply:
• if you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
• if you have experienced a previous episode of aortic dissection (a tear in the aorta wall)
• if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e,g, connective tissue disorders such as Marfan syndrome, or vascular Ehlers- Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis)
• If you feel sudden, severe pain in your abdomen, chest or back, go immediately to an emergency room.
• you have or have ever had a history of mental illness.
• you have problems with your liver or kidneys.
• you have heart disease or problems with your heartbeat.
• you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart).
• you are female or elderly.
• you are taking other medicines that result in abnormal ECG changes
• you have an illness of the nervous system called 'myasthenia gravis' (muscle weakness).
• if you are diabetic or suffer from low blood sugar.

During treatment
When taking this medicine
If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist **immediately.**
If you:
• experience a severe skin rash or allergic reaction, or
• develop severe diarrhoea, (which may be bloody) with stomach pain and fever, or
• notice pain, tenderness, or restricted movement of the tendons, or
• notice numbness or tingling in the hands and feet **stop taking** this medicine and talk to your doctor **straight away.**
Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of Ofloxacin therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), **stop taking**, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

10. Marketed By:

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