Bosch

For Medical Professional only

Tariflox® Tablets
(Ofloxacin U.S.P.)

ٹیری فلوکس ٹیبلیٹس
(اوفلاکساسن یو۔ایس۔پی)

Tariflox® Tablets Forte
(Ofloxacin U.S.P.)

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(اوفلاکساسن یو۔ایس۔پی)

COMPOSITION:
Tariflox 200mg Tablets:
Each coated tablet contains:
Ofloxacin ..... 200mg as Ofloxacin U.S.P.
(Product Specs.: U.S.P.)

Tariflox Forte 400mg Tablets:
Each coated tablet contains:
Ofloxacin ..... 400mg as Ofloxacin U.S.P.
(Product Specs.: U.S.P.)

DESCRIPTION: TARIFLOX (Ofloxacin) is a fluorinated 4-quinolone antimicrobial agent. It is effective in urinary tract infections, respiratory tract infections, skin infections, ENT infections, surgery and in the field of Gynecology.

PHARMACOLOGY: TARIFLOX exerts bactericidal effect in susceptible micro-organisms by inhibiting DNA gyrase (the enzyme that is critical catalyst in the duplication, transcription and repair of bacterial DNA).

INDICATIONS: TARIFLOX and **TARIFLOX FORTE** is indicated for the treatment of the following bacterial infections in adults, if these are due to ofloxacin sensitive pathogens.
Acute chronic or recurrent respiratory tract infections (bronchitis) caused by *Haemophilus influenzae* or other Gram-negative or multi resistant pathogens, as well as by *Staphylococcus aureus*. Pneumonia especially if caused by problem pathogens such as *Klebsiella*, *Proteus*, *Pseudomonas, Legionella* or Staphylococcus. Chronic and recurrent infections of ear, nose and throat, especially if caused by Gram-negative pathogens including Pseudomonas, or by staphylococcus. Acute bacterial exacerbations of chronic bronchitis due to *Haemophilus influenzae* or *Streptococcus pneumoniae*. Community-acquired Pneumonia due to *Haemophilus influenzae* or *Streptococcus pneumoniae.*
- Infections of soft tissue and skin.
- Infections of the bone and joints.
- Infections of the abdominal cavity including the pelvis minor.
- Bacterial enteritis.
- Infections of the kidney, upper and lower urinary tract and genital organs, gonorrhoea, acute uncomplicated urethral and cervical gonorrhea due to *Neisseria gonorrhoeae,* Nongonococcal urethritis and cervicitis due to *Chlamydia trachomatis,* Mixed infections of the urethra and cervix, Acute pelvic inflammatory disease (including severe infection) due to *Chlamydia trachomatis* and *Neisseria gonorrhoeae.*
- Prevention of infections (Prophylaxis of infections, also by selective decontamination of the intestine) in patients with a significant reduction of resistance to infections (e.g. in neutropenic state).

CONTRAINDICATIONS: Ofloxacin is contraindicated in persons with a history of hypersensitivity associated with the use of ofloxacin or any member of the quinolone group of antimicrobial agents. The safety and efficacy of ofloxacin in pediatric patients and adolescents (under the age of 18 years), pregnant women, and lactating women have not been established.

PRECAUTIONS: Adequate hydration of patients receiving ofloxacin should be maintained to prevent the formation of a highly concentrated urine. Administer ofloxacin with caution in the presence of renal or hepatic insufficiency/impairment. In patients with known or suspected renal or hepatic insufficiency/impairment, careful clinical observation and appropriate laboratory studies should be performed prior to and during therapy since elimination of ofloxacin may be reduced. In patients with impaired renal function (creatinine clearance </= 50 mg/mL), alteration of the dosage regimen is necessary. Moderate to severe phototoxicity reactions have been observed in patients exposed to direct sunlight while receiving some drugs in this class, including ofloxacin. Excessive sunlight should be avoided. Therapy should be discontinued if phototoxicity (e.g., a skin eruption) occurs.
As with other quinolones, ofloxacin should be used with caution in any patient with a known or suspected CNS disorder that may predispose to seizures or lower the seizure threshold (e.g., severe cerebral arteriosclerosis, epilepsy) or in the presence of other risk factors that may predispose to seizures or lower the seizure threshold (e.g., certain drug therapy, renal dysfunction).

A possible interaction between oral hypoglycemic drugs (e.g., glyburide/glibenclamide) or with insulin and fluoroquinolone antimicrobial agents have been reported resulting in a potentiation of the hypoglycemic action of these drugs. The mechanism for this interaction is not known. If a hypoglycemic reaction occurs in a patient being treated with ofloxacin, discontinue ofloxacin immediately and consult a physician.

DRUG INTERACTIONS: Administration of quinolones with antacids containing calcium, magnesium, or aluminum, with sucralfate, with divalent or trivalent cations such as iron, or with multivitamins containing zinc, chewable/buffered tablets or the pediatric powder for oral solution may substantially interfere with the absorption of quinolones resulting in systemic levels considerably lower than desired. These agents should not be taken within the two-hour period before or within the two-hour period after ofloxacin administration. Steady-state theophylline levels may increase when ofloxacin and theophylline are administered concurrently. As with other quinolones, concomitant administration of ofloxacin may prolong the half-life of theophylline, elevate serum theophylline levels, and increase the risk of theophylline-related adverse reactions. Theophylline levels should be closely monitored and theophylline dosage adjustments made, if appropriate, when ofloxacin is co-administered. Adverse reactions (including seizures) may occur with or without an elevation in the serum theophylline level. The concomitant administration of a non-steroidal anti-inflammatory drug with a quinolone, including ofloxacin, may increase the risk of CNS stimulation and convulsive seizures. Since disturbances of blood glucose, including hyperglycemia and hypoglycemia, have been reported in patients treated concurrently with quinolones and an antidiabetic agent, careful monitoring of blood glucose is recommended when these agents are used concomitantly.

ADVERSE REACTIONS:
Effects on the gastrointestinal tract: Stomach upset, abdominal pain, loss of appetite, nausea, vomiting, diarrhoea, the possibility of pseudomembranous colitis should be considered in patients in whom severe persistent diarrhoea occur during treatment or in the initial weeks thereafter. This intestinal inflammatory condition induced by antibiotic therapy may be life threatening.
Effects on the Nervous System: Headache, dizziness, sleep disorders very rarely, convulsions, numbness and tingling. Disorders of taste and smell, psychotic reactions such as restlessness, agitation, anxiety, depression, mental confusion, hallucinations.
Hypersensitivity reactions: Cutaneous reactions such as skin eruptions, itching, skin manifestations associated with exposure to strong sunlight (photosensitivity) erythema, swelling of the face, tongue and or larynx, difficult breathing.
Effects on the blood picture: Very rarely, there is a reduction in the numbers of red and white blood cells and/or platelets.
Effects on the liver and biliary tract: Transient impairment of liver function occurs very rarely, increased blood levels of hepatic enzymes and bile pigment with jaundice due to reduced excretion of bile pigment and inflammation of the liver.
Effects on the Kidneys, Urinary Tract and Reproductive Organs: Very rarely there is an impairment of renal functions, for example increase in the blood concentration of substances normally excreted via the kidney (such as creatinine) or an acute inflammation of the kidney.
Miscellaneous Effects: Very rarely rapid heart beat (tachycardia) weakness, muscle, tendon, and joint symptoms such as pain. Traffic warning: Even if used in accordance with the directions, this medicine may affect alertness and reaction time to such an extent that ability to drive, cross the road safely, or operate machinery may be impaired. Concurrent use of alcohol increases this risk.

DOSAGE: Depending on the type and severity of the infection, the dose range for adult is 200mg to 800mg Ofloxacin daily in

two divided doses. In respiratory tract infection the recommended oral dosage is 400 – 600mg daily, while in UTI it is 200 – 600mg daily in two divided doses for 3 -10 days. In severe complicated infections 600mg daily may be needed. In case of non gonococcal urethritis 400mg daily has been used. For the treatment of skin and soft tissue infections and obstetrics & gynecological infections, 200mg twice daily is recommended. A very high percentage of drug is eliminated through urinary excretion, so it is important that dosage should be accordingly reduced in patients with renal insufficiency.

There is no need to increase the dose to 600mg or 800mg Ofloxacin daily in the presence of pathogens of varying sensitivity in severe infections (e.g. of the respiratory tract, bones and joints) or if there is a poor response to the preparation. The same applies to infections with complicating factors. In these cases **TARIFLOX FORTE** should be given as two divided doses daily. Administration of 400-600mg Ofloxacin daily is recommended for prevention of infections in patients with a significant reduction of resistance to infections.

ADMINISTRATION: TARIFLOX and **TARIFLOX FORTE** should be swallowed unchewed with some liquid. It may be taken on an empty stomach or with meals. Patients who are being treated with Ofloxacin should not expose themselves unnecessarily to strong sunlight and should avoid UV rays.

The duration of treatment depends on the response of the causative organism and the clinical picture. As like all antibacterial agents, treatment with **TARIFLOX** and **TARIFLOX FORTE** should be continued for at least 3 days after the body temperature has returned to normal and symptoms have subsided. In most cases of acute infection a course of treatment lasting 7 to 10 days is sufficient. In salmonellosis, the duration of treatment is 7 to 8 days, In shigellosis 3 to 5 days, and in intestinal infections caused by E. coli 3 days on average.

In case of infections with beta-haemolytic streptococci (e.g. purulent tonsillitis or erysipelas) whose sensitivity has been demonstrated, treatment must be continued for not less than 10 days so as to safeguard the patient against late complications such as rheumatic fever or glomerulonephritis (inflammation of the renal glomeruli). For uncomplicated infections of the lower urinary tract, 3 days treatment is sufficient. The duration of treatment should not exceed 2 months.

HOW SUPPLIED:

TARIFLOX 200mg Tablet (Ofloxacin U.S.P.) in Cold Form-Cold Seal blister pack of 1x10's Tablets.

TARIFLOX FORTE 400mg Tablet (Ofloxacin U.S.P.) in Cold Form-Cold Seal blister pack of 2x5's Tablets.

STORAGE

Protect from heat, sunlight & moisture, store below 30°C.

The expiration date refer to the product correctly stored at the required condition.

Keep out of the reach of children.

Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.

To be sold on prescription of a registered medical practitioner only.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: دھوپ، گرمی اور نمی سے محفوظ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

بچوں کی پہنچ سے دُور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

Manufactured by:
Bosch Pharmaceuticals (Pvt) Ltd.
221-223, Sector 23, Korangi Industrial Area,
Karachi - Pakistan

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