AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

LEAFLET

4. The concomitant administration of quinolones including Norfloxacin with glyburide (a sulfonylurea agent) has, on rare occasions, resulted in severe hypoglycemia. Therefore, monitoring of blood glucose is recommended when these agents are co-administered.
5. The concomitant use of Nitrofurantoin is not recommended since Nitrofurantoin may antagonize the antibacterial effect of Norfloxacin in the urinary tract.
6. Multivitamins, or other products containing iron or zinc, antacids or sucralfate, should not be administered concomitantly with, or within 2 hours of, the administration of Norfloxacin, because they may interfere with absorption resulting in lower serum and urine levels of Norfloxacin.
7. Some quinolones have also been shown to interfere with the metabolism of caffeine. This may lead to reduced clearance of caffeine and a prolongation of the plasma half-life that may lead to accumulation of caffeine in plasma when products containing caffeine are consumed while taking Norfloxacin.

PREGNANCY :
Norfloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

STORAGE:
Store under normal storage conditions (15°C to 30°C).

Protect from light.

Keep all medicines out of reach of children.

PRESENTATION:
Jar pack of 1000 Tablets.
Blister pack of 10 x 10 Tablets.
Blister pack of 100 x 10 Tablets.

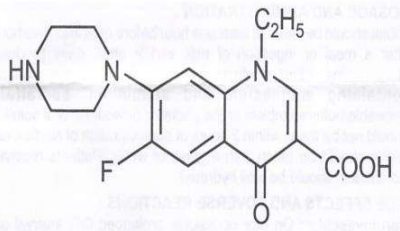
Manufactured in India by:
AGOG PHARMA LTD.
Plot No. 33, Sector II, The Vasai Taluka Indl.
Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.

AGONOR

Norfloxacin Tablets BP 400 mg

COMPOSITION :
Each film coated tablet contains:
Norfloxacin BP..... 400 mg
Excipients ..... q.s.

DESCRIPTION :
Norfloxacin is a synthetic, broad-spectrum antibacterial agent for oral administration. Norfloxacin, a fluoroquinolone, is 1-ethyl-6-fluoro-1, 4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid. Its empirical formula is C16H18FN3O3 and the structural formula is:



CLINICAL PHARMACOLOGY :
Absorption is rapid following single doses of 200 mg, 400 mg and 800 mg. The presence of food and/or dairy products may decrease absorption. The effective half-life of Norfloxacin in serum and plasma is 3-4 hours. Steady-state concentrations of Norfloxacin will be attained within two days of dosing. In healthy elderly volunteers (65-75 years of age with normal renal function for their age), Norfloxacin is eliminated more slowly because of their slightly decreased renal function. Drug absorption appears unaffected. However, the effective half-life of Norfloxacin in these elderly subjects is 4 hours. Norfloxacin is eliminated through metabolism, biliary excretion, and renal excretion.

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INDICATIONS AND USAGE :
Norfloxacin is indicated for the treatment of following infections:

1. Urinary tract infections

Urinary tract infections (including cystitis) due to Enterococcus faecalis, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Staphylococcus epidermidis, Staphylococcus saprophyticus, Citrobacter freundii, Enterobacter aerogenes, Enterobacter cloacae, Proteus vulgaris, Staphylococcus aureus, or Streptococcus agalactiae.

2. Sexually transmitted diseases

Uncomplicated urethral and cervical gonorrhea due to Neisseria gonorrhoeae.

3. Prostatitis

Prostatitis due to Escherichia coli.

DOSAGE AND ADMINISTRATION :
Tablet should be taken at least one hour before or at least two hours after a meal or ingestion of milk and/or other dairy products. Multivitamins, other products containing iron or zinc, antacids containing magnesium and aluminium, sucralfate, chewable/buffered tablets or the pediatric powder for oral solution, should not be taken within 2 hours of administration of Norfloxacin. Tablet should be taken with a glass of water. Patients receiving Norfloxacin should be well hydrated.

SIDE EFFECTS AND ADVERSE REACTIONS :
Cardiovascular: On rare occasions, prolonged QTc interval and ventricular arrhythmia.
Hepatic: Hepatic failure, including fatal cases.
Renal: Interstitial nephritis, renal failure.
Nervous System/Psychiatric: Peripheral neuropathy, Guillain-Barré syndrome, ataxia, paresthesia, hypoesthesia, psychic disturbances including psychotic reactions and confusion.
Musculoskeletal: Tendinitis, tendon rupture; exacerbation of myasthenia gravis, elevated creatine kinase, muscle spasms.
Hematologic: Neutropenia; leukopenia; Agranulocytosis; hemolytic anaemia, sometimes associated with glucose-6-phosphate dehydrogenase deficiency; thrombocytopenia.
Hypersensitivity Reactions: Hypersensitivity reactions have been reported including anaphylactoid reactions, angioedema, dyspnea, vasculitis, urticaria, arthritis, arthralgia and myalgia.
Skin: Toxic epidermal necrolysis, Stevens-Johnson syndrome and erythema multiforme, exfoliative dermatitis, photosensitivity/phototoxicity reactions, leukocytoclastic vasculitis, drug rash with eosinophilia and systemic symptoms.
Gastrointestinal: Pseudomembranous colitis, hepatitis, jaundice including cholestatic jaundice and elevated liver function tests, pancreatitis (rare), stomatitis. The onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment.
Special Senses: Hearing loss, tinnitus, diplopia, dysgeusia.
Other adverse events reported with quinolones include: agranulocytosis, albuminuria, candiduria, crystalluria, cylindruria, dysphagia, elevation of blood glucose, elevation of serum cholesterol, elevation of serum potassium, elevation of serum triglycerides, hematuria, hepatic necrosis, symptomatic hypoglycemia, nystagmus, postural hypotension, prolongation of prothrombin time, and vaginal candidiasis.

OVERDOSAGE AND TREATMENT :
In the event of acute overdosage, the stomach should be emptied by inducing vomiting or by gastric lavage, and the patient carefully observed and given symptomatic and supportive treatment. Adequate hydration must be maintained.

CONTRAINDICATIONS :
Norfloxacin is contraindicated in persons with a history of hypersensitivity, tendinitis, or tendon rupture associated with the use of Norfloxacin or any member of the quinolone group of antimicrobial agents.

DRUG INTERACTIONS :
1. Elevated plasma levels of theophylline have been reported with concomitant quinolone use. Therefore theophylline-related side effects in patients on concomitant therapy with Norfloxacin and theophylline.
2. Elevated serum levels of cyclosporine have been reported with concomitant use of cyclosporine with Norfloxacin.
3. Quinolones, including Norfloxacin, may enhance the effects of oral anticoagulants, including warfarin or its derivatives or similar agents.