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338

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Evaflox

Ofloxacin Tablets USP

1. NAME OF THE MEDICAL PRODUCT

1.1 Product name

Evaflox 200
Evaflox 400

1.2 Strength

200 mg and 400 mg

1.3 Pharmaceutical Dosage form

Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 General description

Ofloxacin, the active ingredient of Evaflox is a bactericidal quinolone antibiotic.

2.2 Qualitative and quantitative composition

Evaflox 200: Each film coated tablet contains: Ofloxacin USP 200 mg
Evaflox 400: Each film coated tablet contains: Ofloxacin USP 400 mg
For the full list of excipients, see section 6.1

3. Pharmaceutical Form

Evaflox 200: Light pink, round, biconvex film coated tablet.
Evaflox 400: Light pink, oblong, bicovex, film coated tablet.

4. Clinical particulars

4.1 Therapeutic indications

For the treatment of infections caused by susceptible strains of micro-organisms in infections of the urinary tract, respiratory tract, ear, nose and throat, abdominal cavity and skin and soft tissues.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Indication	Daily dosage	Duration of treatment
Uncomplicated infections of the lower urinary tract	200 mg	The duration of treatment depends on the response of the causative organism and on the clinical picture. As with antibacterial treatment in general, it is recommended that treatment with Evaflox be continued for at least 3 days after the body temperature has returned to normal and the 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 usually 7 to 8 days, in shigellosis 3 to 5 days and in intestinal infections caused by E.coli 3 days.
Infections of the upper urinary tract and reproductive organs	400 mg	
Infections of the respiratory tract and of the ear, nose and throat	400 mg	
Infections of the skin and the soft tissues	400 mg	
Abdominal infections		

Dose in elderly: No adjustment of dosage is required in the elderly other than that imposed by consideration of renal function.
A daily dose of upto 400 mg EVAFLOX may be taken as a single dose, preferably in the morning. Larger doses must be divided into two separate doses at equal intervals.
Depending on the severity of the infection and on the presence of complicating factors or pathogens of moderate susceptibility, it may be necessary to increase the dose to upto 2 x 400 mg tablets daily.
Dosage in patients with impaired renal function: In patients with impaired renal function, the following dosages are recommended.
The initial dose is the same as for patients with normal renal function, whereas the maintenance dose should be reduced as follows :

Creatinine clearance	Maintenance dose
50-20 ml/min	100-200 mg EVAFLOX every 24 hours
<20 ml/min	100 mg EVAFLOX every 24 hours
Haemodialysis or peritoneal dialysis	100 mg EVAFLOX every 24 hours

Dosage in patients with impaired liver function: The excretion of ofloxacin may be reduced in patients with severe impairment of liver function (e.g. cirrhosis with ascites). A maximum daily dose of 400 mg ofloxacin should, therefore not be exceeded.
Until further experience is available, the duration of treatment should not exceed 2 months.

Method of administration

EVAFLOX tablets should be swallowed without chewing with sufficient amounts of liquid (approx. 1/2 glass). They may be taken on an empty stomach or with meals.

4.3 Contraindications

EVAFLOX must not be used in
1. Pregnancy and lactation
2. Children and adolescents in the growth phase
3. Epileptics as well as in patients with a lowered cerebral seizure threshold due to pre-existing central nervous system lesions
4. Patients hypersensitive to ofloxacin, other quinolones or any of the excipients

4.4 Special warning and precautions for use

♦ Patients with a history of severe adverse reactions e.g., anaphylaxis, tendinitis with rupture of the affected tendon, severe neurological reactions to other quinolones may be at increased risk of similar reactions to EVAFLOX.
♦ Administration of antibiotics, especially if prolonged, may lead to the proliferation of resistant microorganisms. The patient's condition must therefore be checked at regular intervals. If a secondary infection occurs, appropriate measures must be taken.
♦ Patients undergoing treatment with EVAFLOX are advised not to expose themselves unnecessarily to strong sunlight and to avoid UV rays (sunray lamp, solarium). Otherwise, skin and nail reactions may occur due to photosensitivity.
♦ Some adverse effects may impair the ability to concentrate and react, and therefore, constitute a risk in situations where these abilities are of particular importance (e.g. driving a car or operating machinery).
♦ **Exacerbation of myasthenia gravis:**
Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in person with myasthenia gravis. Post marketing serious adverse events, including deaths and requirement for ventilator support have been associated with fluoroquinolones use in persons with myasthenia gravis. Avoid fluoroquinolones in patients with known history of myasthenia gravis.
The use of Ofloxacin should be avoided in patients who have experienced serious adverse reactions in the past when using fluoroquinolones containing products. Treatment of these patients with Ofloxacin should only be initiated in the absence of alternate treatment options and after careful benefits/risk assessment.
Aortic aneurysm and dissection
Epidemiologic studies report an increased risk of aortic aneurysm and dissection after intake of fluoroquinolones, particularly in the older population. Therefore, fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients with positive family history of aneurysm disease, or in patients diagnosed with pre-existing aortic aneurysm and/or aortic dissection, or in presence of other risk factors or conditions predisposing for aortic aneurysm and dissection (e.g. Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, hypertension, known atherosclerosis).
In case of sudden abdominal, chest or back pain, patients should be advised to immediately consult a physician in an emergency department.
Prolonged, disabling and potentially irreversible serious adverse drug reactions
Very rare cases of prolonged (continuing months or years), disabling and potentially irreversible serious adverse drug reactions affecting different, sometimes multiple body systems (musculoskeletal, nervous, psychiatric and senses) have been reported in patients receiving fluoroquinolones irrespective of their age and pre-existing risk factors. Ofloxacin should be discontinued immediately at the first signs or symptoms of any serious adverse reaction and patients should be advised to contact their prescriber for advice.
Tendinitis and tendon rupture
Tendinitis and tendon rupture (especially but not limited to Achilles tendon), sometimes bilateral, may occur as early as within 48 hours of starting treatment with fluoroquinolones and have been reported to occur even up to several months after discontinuation of treatment. The risk of tendinitis and tendon rupture is increased in older patients (above 60 years of age), with renal impairment, patients with solid organ transplants, and those treated concurrently with corticosteroids. Therefore, concomitant use of corticosteroids should be avoided.At the first sign of tendinitis (e.g. painful swelling, inflammation) the treatment with Ofloxacin should be discontinued and alternative treatment should be considered. The affected limb(s) should be appropriately treated (e.g. immobilisation). Corticosteroids should not be used if signs of tendinopathy occur.
Peripheral neuropathy
Cases of sensory or sensorimotor polyneuropathy resulting in paraesthesia, hypaesthesia, dysesthesia, or weakness have been reported in patients receiving quinolones and fluoroquinolones. Patients under treatment with Ofloxacin should be advised to inform their doctor and pharmacist prior to continuing treatment if symptoms of neuropathy such as pain, burning, tingling, numbness, or weakness develop in order to prevent the development of potentially irreversible condition(see section Adverse Effects).
Psychiatric reactions
Psychiatric reactions may occur even after the first administration of fluoroquinolones, including Evaflox. In rare cases, depression or psychotic reactions can progress to suicidal ideations/thoughts and self-injurious behaviour, such as attempted or completed suicide (see section 'Undesirable effects'). In the event that the patient develops these reactions, Evaflox should be discontinued and appropriate measures instituted. Caution is recommended if Evaflox is to be used in psychotic patients or in patients with a history of psychiatric disease.

4.5 Interaction with other medical products and other forms of interactions

♦ With some medicines, taken concurrently, an attenuation of the effect of EVAFLOX tablets must be taken into account e.g. mineral antacids (containing aluminium or magnesium), sucralfate, or iron preparations and calcium.
For this reason, EVAFLOX tablets must be taken about 2 hours before taking such preparations.
♦ With drugs that lower the seizure threshold, there are indications of a pronounced lowering of the cerebral seizure threshold e.g. theophylline.
♦ EVAFLOX may cause a slight increase in serum concentrations of glibenclamide administered concurrently. Therefore, patients should be closely monitored.
♦ Concurrent administration of chloroquine with quinolones should be undertaken with care as both drugs are neurotoxic.
♦ Mutual impairment of excretion and an increase in serum levels must be considered when quinolones are administered together with other drugs that also undergo renal tubular secretion particularly when administered in high doses eg: probenecid, cimetidine, furosemide or methotrexate.
♦ In patients who are treated with quinolones, an increase in the effect of coumarin derivatives cannot be ruled out. Therefore, patients undergoing concurrent treatment with coumarin derivatives like warfarin should be closely monitored.
♦ Tendinitis and tendon rupture has been observed in patients treated concurrently with corticosteroids.
Interference with laboratory tests
Determination of opiates or porphyrins in urine may give false-positive results during treatment with EVAFLOX.

4.6 Fertility, pregnancy and lactation

Evaflox must not be used in pregnancy and lactation.

4.7 Effects on ability to drive and use machine

No studies on the effects of ofloxacin on the ability to drive and use machines have been performed. Some undesirable effects (e.g., dizziness/vertigo, drowsiness, visual disturbances) may impair the patient's ability to concentrate and react, and therefore may constitute a risk in situations where these abilities are of special importance (e.g., driving a car or operating machinery).

4.8 Undesirable effects

General
♦ Hypersensitivity to light may develop in very rare cases. This may resemble severe sunburn and in some cases also involve the nails (discolouration, loosening).
♦ Fever, eosinophilia and allergic inflammation of the lungs (allergic pneumonitis) may develop in very rare cases.
♦ Anaphylactic or anaphylactoid reactions (rapidly developing allergy or allergy-like hypersensitivity reactions) may occur in very rare instances, but sometimes even after the first dose. These may manifest themselves in a rise in blood pressure, sweating, burning sensation in the eyes, dry cough and nasal catarrh. These may also be accompanied by swelling of the skin and mucous membranes (angio-oedema) involving the face, tongue and larynx (symptoms: hoarseness, difficulty in breathing). In the most serious cases, severe respiratory distress (also caused by bronchial spasm) or circulatory collapse (shock) may develop. In the event of such reactions, treatment with EVAFLOX must be halted immediately and medical treatment initiated.
♦ In very rare cases, muscular complaints such as pain or weakness (of special significance in, e.g. patients with myasthenia gravis) may occur. In isolated cases, these may be

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symptoms of muscle disease (rhabdomyolysis) entailing destruction of muscle tissue, which, in some cases, can lead to muscular atrophy and acute renal failure. Very rarely, Joint and tendon discomfort (e.g. pain) may occur.
♦ Inflammation of tendons (tendinitis) and rupture (e.g. Achilles tendon) may occur in isolated instances during treatment with quinolones. If tendinitis is suspected, treatment with EVAFLOX must be halted immediately and appropriate treatment must be initiated for the affected tendon.
♦ EVAFLOX may trigger an attack of porphyria in predisposed patients.
♦ Hyper or hypoglycaemia may occur in isolated cases.
♦ Administration of antibiotics, especially if prolonged, may lead to the proliferation of resistant microorganisms.
♦ Except in very rare instances (e.g. isolated cases of smell, taste and hearing disorders), the adverse effects observed subsided after discontinuation of EVAFLOX.
Systemic :
1. Gastrointestinal tract : During treatment with EVAFLOX, stomach upsets, abdominal pain, loss of appetite, nausea, vomiting, or diarrhoea may occur.
a) Diarrhoea may sometimes be a symptom of enterocolitis, which may, be accompanied by blood in stools.
b) Pseudomembranous colitis (in most cases is due to Clostridium difficile). This possibility must be considered in patients in whom severe, persistent diarrhoea occurs during treatment or in the initial weeks thereafter. If suspected, administration of EVAFLOX must be halted immediately. Drugs that inhibit intestinal motility must not be taken in such cases.
c) Liver : Rarely, impairment of liver function with jaundice may occur. Very rarely, cholestatic jaundice, hepatitis or severe liver damage may develop.
2. Nervous system :
♦ Headache, dizziness, sleep disorders, agitation and confusion may occur.
♦ In rare cases, drowsiness, unsteadiness of gait and tremor (due to disorders of muscular co-ordination), extrapyramidal symptoms (increased or decreased muscle tone, involuntary movements of the face and body, tremor at rest, a decrease in spontaneous movements or slowness in initiating movements) are also seen.
♦ Convulsions, numbness and tingling (paraesthesia or hyperaesthesia) may rarely occur.
♦ Rarely, visual disorders such as blurred vision, double vision, and abnormal colour vision have been reported.
♦ Disorders of taste and smell (including loss of taste and smell) may develop.
♦ Disorders of hearing (in exceptional cases even loss of hearing) and tinnitus are rare with EVAFLOX.
♦ In very rare cases, hallucinations, anxiety, depression and psychotic reactions may occur. Certain psychotic reactions may, in some cases, lead to self-endangering behavior. In the event of such reactions, even after the first dose, EVAFLOX must be discontinued immediately.
3. Cardiovascular system : Ingestion of EVAFLOX may be followed by tachycardia and temporary hypotension. In rare cases, as a consequence of pronounced hypotension, circulatory collapse is possible.
4. Blood : Very rarely, a reduction in the numbers of both red and white blood cells (this can include the absence of certain white blood cells) and/or of platelets (anaemia, leucopenia including agranulocytosis, thrombocytopenia, pancytopenia) may occur. In some cases, these changes result from bone-marrow depression. Very rarely, haemolytic anaemia may develop.
5. Kidneys : Rarely, impairment of renal functions, like an increase in serum creatinine may develop. Isolated cases of kidney inflammation have been seen. This interstitial nephritis may progress to acute renal failure.
***6. Skin,* mucous membranes and other reactions :** Cutaneous and mucosal reactions such as itching and skin rashes (in exceptional cases, with blisters or small pus-filled vesicles) may develop. In very rare cases reddening of the skin accompanied by burning, severe skin reactions (erythema multiforme, Stevens-Johnson syndrome and Lyell's syndrome) and inflammation of the vessels (vasculitis) can occur and may manifest itself in the form of bleeding under the skin looking like tiny red dots (petechiae), or blood-filled blisters (haemorrhagic bullae) or small nodules with crust formation. It can also lead to skin lesions including irreversible damage (necrosis) in exceptional cases. Vasculitis may also involve internal organs.
Please consult a physician if you notice any of the adverse effects listed in this package insert or any other undesired effects or unexpected changes.
Post Marketing Experience: *exacerbation of myasthenia gravis*
Musculoskeletal and connective tissue disorders*
Nervous system disorders*
General disorders and administrative site site conditions*
Psychiatric disorders*
Eye disorders*
Ear and labyrinth disorders*
*Very rare cases of prolonged (up to months or years), disabling and potentially irreversible serious drug reactions affecting several, sometimes multiple, system organ classes and senses (including reactions such as tendinitis, tendon rupture, arthralgia, pain in extremities, gait disturbance, neuropathies associated with paraesthesia, depression, fatigue, memory impairment, sleep disorders, and impairment of hearing, vision, taste and smell) have been reported in association with the use of fluoroquinolones in some cases irrespective of pre-existing risk factors (see section Warnings and Precautions).
Psychiatric disorders
Rare: Psychotic disorder (for e.g.hallucination)
Very Rare: Psychotic behaviour
Frequency not known (cannot be estimated from the available data): Psychotic disorders and depression with self-endangering behavior including suicidal ideation or suicide attempt

4.9 Overdose

Information on overdosage with ofloxacin is limited. The most important signs to be expected following acute overdosage are CNS symptoms like drowsiness, dizziness, confusion, impairment of consciousness, hot and cold flushes and subjective facial swelling, numbness, slurring of speech and mild to moderate disorientation. Also the gastrointestinal symptoms such as nausea, mucosal erosions occur with ofloxacin.
Treatment of overdosage:
In an event of overdosage, stomach should be emptied by gastric lavage and symptomatic treatment should be given. The patient should be observed and appropriate hydration maintained. No specific antidote exists for ofloxacin.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

A primary bacterial target of ofloxacin, like other quinolones is the enzyme DNA gyrase. DNA gyrase contains four subunits: two 'A" and two 'B' subunits. Genetic and biochemical studies have identified the A subunit of DNA gyrase (type II topoisomerase) as the target of quinolones. Quinolones inhibit all the enzymatic activities of DNA gyrase, including inhibition of negative supercoiling, the joining and seperation of interlocked DNA circles.
In addition, ofloxacin has a second mechanism of action, independent of its effect on RNA synthesis. Rifampicin which exhibits RNA synthesis prevents bactericidal action of quinolones such as nalidixic acid but has much less effect on the action of ofloxacin.
Ofloxacin has bactericidal activity against bacteria, in general the minimal bactericidal concentration (MBC) is the same as, or no more than, one fold concentration higher than the minimal concentration (MNC).
Antibacterial spectrum:
I Highly susceptible organisms:
Enterobacteriaceae: Escherichia coli, Enterobacter, Klebsiella, Proteus, Salmonella, Shigella, Serratia, Citrobacter.
Staphylococci: Staphylococcus aureus (including methicillin-resistant Staph.), Staphylococcus epidermidis.
Neisseriae: Neisseria gonorrhoeae (including ampicillin resistant strains), Neisseria meningitidis.
II Susceptible organisms:
Campylobacter, Aeromonas, Vibrio cholerae, Yersinia enterocolitica, Helicobacter pylori, Gardnerella vaginalis.
III Organisms with variable susceptibility:
Pseudomonas aeruginosa, Enterococci Streptococci (Strept. pyogenes, Strept. pneumoniae, Strept. viridans) Mycoplasma (Mycoplasma hominis, Mycoplasma pneumoniae) Mycobacteria (Mycobacterium tuberculosis, Mycobacterium fortuitum)
IV Usually resistant organisms:
Ureaplasma urealyticum, Nocardia asteroides, and anaerobes (e.g.: Bacteroides, Peptococcus, Peptostreptococcus, Fusobacterium, Clostridium difficile)
V Resistant organisms:
Treponema pallidum.

5.2 Pharmacokinetic Properties

Ofloxacin is essentially 100% absorbed following oral administration. Very high concentrations of the drug are achieved in serum and most body fluids and tissues. These levels are sufficient to inhibit most bacteria at the site of infection.
Ofloxacin is rapidly and uniformly absorbed after oral administration. There is negligible presystemic metabolism. Maximum serum concentration (Tmax) are usually achieved in under 2 h (0.5-1.6h). Following an oral dose of 100 mg ofloxacin, the peak serum concentration (Cmax) is 1.3 mg.l-1, which increase to 3.8 mg.l-1 with 300 mg, 5.5 mg.l-1 with 400 mg, and 7-10 mg.l-1 with 600 mg respectively. The plasma elimination half-life is about 6-7h.
The apparent volume of distribution is 1-2.5 l.kg-1. More than 70% of the drug is recovered unchanged in the urine in 24h, and 80% in 48h. Renal clearance is 180-190 ml.min-1. Less than 10% of the dose is received as metabolites. Ofloxacin exhibits low plasma protein binding (20-25%).
Ofloxacin penetrates well into many body fluids. Very high concentrations of the drug are found in saliva, nasal secretions, tears, blister fluid, bronchial secretions, and sputum. Ofloxacin penetration into sputum and bronchial secretion is 70-115%. Bronchial secretion penetration studies suggest that ofloxacin, at a 400 mg oral dose, is likely to achieve therapeutic activity against respiratory pathogens. After oral administration of ofloxacin 200 mg, 42-71% penetration is found in the cerebrospinal fluid.
Ofloxacin penetration into lung tissue is quite high (with tissue/serum levels of 17.7/8.7 mg.l-1, to give a ratio of 2). Ofloxacin penetration into bone has been studied. The ratio of the bone to serum levels was 0.61 %. Penetration of up to 112 % into prostatic tissue were reported.
Metabolism plays a very limited role in the elimination of ofloxacin. Three metabolites of ofloxacin have been found: ofloxacin-glucuronide, desmethyl-ofloxacin, and ofloxacin-N-oxide.
Ofloxacin is extensively excreted by the kidneys as the unchanged drug with up to 80 % of an oral dose eliminated in the urine as the parent compound within 48h. Urinary recovery of desmethyl and N-oxide ofloxacin accounts for less than 5 % of an administered oral dose.

5.3 Preclinical safety Data

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6. Pharmaceutical Particulars

6.1 List of excipients

Lactose Monohydrate BP, Maize Starch BP, Purified Talc BP,Croscarmellose Sodium USPNF , Colloidal Silicon dioxide BP , Magnesium Stearate BP ,Purified water USP , Hydroxypropyl Methyl cellulose BP , Macrogol 400 BP ,Dichloromethane BP , Opadry 04B540002 Pink.

6.2 Incompatibilities

None

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at temperature not exceeding 30°C. Protected from light and moisture.
Keep medicines out of the reach of children.

6.5 Nature and contents of container

Blister of 6 tablets.

7. Marketing Authorization Holder

Healol Pharmaceuticals Sdn Bhd.
(Reg.No. 298878-K)
74-3, Jalan Wangsa Delima 6,
KLSC Wangsa Maju,
53300 Kuala Lumper, Malaysia.

8. Marketing Authorization Numbers

Evaflox 200: MAL 20040755AZ
Evaflox 400: MAL 20040756AZ

9. Date of first authorization/renewal of the authorization

13.11.2019

10. Date of revision of the text

November 2025

Product	MAL No.:
Evaflox 200	MAL 20040755AZ
Evaflox 400	MAL 20040756AZ

Manufactured in India by:

UNICHEM LABORATORIES LTD.
Unit-II, Village Bhatauli Kalan, Baddi, Dist. Solan (H.P.) - 173 205.

Date of revision of insert:
November 2025
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560 mm

560 mm

Company Name : UNICHEM LABORATORIES LTD.		**Date:** 18-11-2025	
Agency Name: UNICORN CREATION		**Open Size:** 100 x 560 mm	
Product: Evaflox Tablet Leaflet - With USP in Generic name	**Packing:** NA	**Prefolded Size:** ------	
Item Code: 13012955	**Location:** Baddi-II	**No. of prefolds:** ------	
Specification: 40 gsm bible Paper (Front Back Printing). ITC Pharmaprint.		**Old Item Code:** 13012955	**Pharmacode :** 338
Colour Code: Text in black		**Market:** Malaysia	
Font Type: Myriad Pro		**Font Size:** 7 pt	
Reason: New word file received & Increased font size to 7pt & Pharmacode added.			