

OFLO TABLET

Ofloxacin (200mg, 400 mg)

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What Oflo is used for

Oflo is used for the treatment of upper and lower urinary tract infections; lower respiratory tract infections; uncomplicated urinary tract and vaginal opening bacterial infection; inflammation of urinary tract and vaginal opening, skin and soft tissue infections.

How Oflo works

Oflo contain a medicine called ofloxacin. This belongs to a group of medicines called antibiotics. It works by killing bacteria that cause infections.

Before you use Oflo

- When you must not use it

Do not take Oflo if:

- You are allergic (hypersensitive) to ofloxacin or any of the other ingredients of Oflo tablets. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Pregnancy and lactation

Do not take this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding or planning to breast-feed

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

- Before you start use it

Tell your doctor if you have any of the following:

- You have liver or kidney problems
- You are taking medicines that can affect your heart (see section Taking other medicines)
- You have or have ever had any mental health problems
- You suffer from a condition called 'myasthenia gravis' (muscle weakness)
- You have been told by your doctor that you cannot tolerate some sugars.

- You have experienced sensitivities to other quinolone antibacterial agents.

You should not take fluoroquinolone antibacterial medicines, including Oflo, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Oflo.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Oflo and some other medicines can affect the way each other work.

In particular, tell your doctor if you are taking the following medicine:

- Co-administered magnesium/ aluminium antacids, sucralfate or iron preparations can reduce absorption. Therefore, ofloxacin should be taken 2 hours before such preparations.
- Some antimicrobials (that belong to the group of macrolides).
- Some antipsychotics.
- Glibenclamide
- Anticoagulants
- Probenecid
- Cimetidine
- Frusemide
- Methotrexate

How to use Oflo

- How much to use

- Your doctor will decide on how many Oflo you should take
- The dose will depend on the type of infection you have.

The usual dose for adults, including the elderly, is between 200 mg and 800 mg each day. The dose depends on the location and type of infection:

- Kidney or bladder infections (urinary tract): 200 to 800 mg each day
- Chest or lung: 400 to 800 mg each day
- Male or female sex organ infections (genital tract): 400 mg each day
- Gonorrhoea A single dose of 400 mg
- Skin and soft tissue infections: 400 to 800 mg each day

Kidney or liver problems

If you have any kidney or liver problems you may be given a lower dose.

Children and Adolescents:

This medicine should not be given to children or adolescents.

- When to use it

- The length of your treatment will depend on how serious your infection is.
- The medicine is usually taken for 5 to 10 days and treatment should not be longer than 2 months.
- Doses up to 400 mg are taken as a single dose in the morning.
- Higher doses should be taken in two doses, one in the morning and one in the evening.

- How long to use it

Continue taking Oflo for as long as your doctor recommends.

- If you forget to use it

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten tablet.

- If you use too much (overdose)

If you take more Oflo than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling confused or dizzy, loss of consciousness, fits, feeling sick or blood in your stools.

While you are using it

You may experience mental health problems even when taking/ using fluoroquinolone antibiotics, including OFLO for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behaviour such as suicide attempts. If you develop such reactions, stop taking/ using OFLO and inform your doctor immediately.

- Things you must do

Taking Oflo may affect the results of some urine tests. If you are going to have a urine test, it is important to tell your doctor you are taking Oflo.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Oflo.

Tell your doctor immediately if you become pregnant while taking this medication.

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- Things you must not do

Do not drink alcohol while taking Oflo. This is because it may make you feel dizzy or sleepy.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Oflo to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

You may feel sleepy or dizzy or have problems with your eyesight while taking this medicine. If this happens, do not drive or use any tools or machines.

Oflo contain lactose. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking Oflo.

Patients being treated with ofloxacin should not be expose themselves unnecessarily to strong sunlight and should avoid UV rays (sunlamps, solarium).

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including Oflo, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your healthcare providers.
- Pain in your joints or swelling in your shoulder, arms or legs.
- Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the leg or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell, or hearing

Tell your healthcare providers if you have had one of the above effects during or shortly after taking a fluoroquinolone – this means you should avoid them in the future. You and your healthcare

providers will decide on continuing the treatment considering also an antibiotic from another class.

Tendinitis and tendon rupture

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 Oflo therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Oflo, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

Peripheral neuropathy

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking Oflo and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition

Side effects

Like all medicines, Oflo can cause side effects although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

- Very Rare (affects less than 1 in 10,000 people)
- Rare (affects less than 1 in 1000 people)
- Frequency Unknown

Digestive and liver side effects:

- Common: Nausea and vomiting, diarrhoea, abdominal pain, gastric symptoms. (Diarrhoea may sometimes be a symptom of enterocolitis which may, in some cases, be haemorrhagic).
- Rare: Loss of appetite, increase in liver enzymes and/or bilirubin.
- Very rare: cholestatic jaundice, hepatitis or severe liver damage may develop.

Central nervous system:

- Common: Headache, dizziness, sleep disorders, restlessness.
- Rare: Confusion, nightmares, anxiety,

depression, hallucinations and psychotic reactions, drowsiness, unsteady gait and tremor (due to disorders of muscular co-ordination), neuropathy, numbness and paraesthesia or hypoesthesia, visual disturbances, disturbances of taste and smell (including, in exceptional cases, loss of function), extrapyramidal symptoms.

- Very rare: Convulsions, hearing disorders (including, in exceptional cases, loss of hearing). These reactions have occurred in some patients after the first dose of ofloxacin. In such cases, discontinue treatment immediately.

Psychiatric disorders:

- Rare: Psychotic reactions with a risk of having suicidal thoughts or actions, hallucination, depression
- Very Rare: Psychotic behaviour
- Frequency not known (cannot be estimated from the available data): Psychotic reactions with a risk of having suicidal thoughts or actions

Cardiovascular system:

- Common: Tachycardia and a temporary decrease in blood pressure have been reported.
- Rare: circulatory collapse (due to pronounced drop in blood pressure).

Haematological:

- Very rare: anaemia, leucopenia (including agranulocytosis), thrombocytopenia, pancytopenia. Only in some cases are these due to bone marrow depression. In very rare cases, haemolytic anaemia may develop.

Renal:

- Rare: Disturbances of kidney function.
- Isolated cases: Acute interstitial nephritis, or an increase in serum creatinine, which may progress to acute renal failure.

Allergic and skin side effects:

- Common: Skin rash, itching.
- Very rare: Rash on exposure to strong sunlight. Hypersensitivity reactions, immediate or delayed, usually involving the skin (e.g., erythema multiforme, Stevens-Johnson syndrome, Lyell's syndrome, and vasculitis), skin lesions, tachycardia, fever, dyspnoea, shock, angioneurotic oedema, vasculitic reactions, eosinophilia.
- Isolated cases: Pneumonitis.

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Other side effects:

- Rare: Malaise.
- Very rare: Excessive rise or fall in blood-sugar levels. Weakness, joint and muscle pains (in isolated cases these may be symptoms of rhabdomyolysis).
- Isolated cases: Tendon discomfort, including inflammation and rupture of tendons (e.g., the Achilles tendon) particularly in patients treated concurrently with corticosteroids. In the event of signs of inflammation of a tendon, treatment with Ofloxacin must be halted immediately and appropriate treatment must be initiated for the affected tendon. The possibility cannot be ruled out that ofloxacin may trigger an attack of porphyria in predisposed patients.
- Exacerbation of myasthenia gravis

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves – in a small proportion of patients, these side effects caused long lasting or permanent disability (See section Before you start to use it and Things to be careful of)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers-> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Oflo

- Storage

Store below 30°C. Protect from light and moisture

Keep this medicine in a safe place where children cannot see or reach it.

Keep the blister strip in the outer carton in order to protect from moisture.

- Disposal

Do not use Oflo tablets after the expiry date which is stated on the label. The expiry refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Oflo 200

White to yellowish white coloured round biconvex film coated tablets.

Oflo 400

Pale yellow to yellow coloured round, biconvex film coated tablets.

- Ingredients

- Active ingredient Ofloxacin USP

- Inactive ingredients

- Purified Talc BP
- Sodium Methyl Hydroxy Benzoate
- Purified Talc
- Colloidal Anhydrous Silica
- Magnesium Stearate
- Maize Starch
- Microcrystalline Cellulose
- Croscarmellose Sodium
- Opadry White II
- Purified Water BP

MAL number:

Oflo 200: MAL06011706AZ

Oflo 400: MAL06011704AZ

Manufacturer

Unique Pharmaceuticals Laboratories
(A Division of J.B. Chemicals & Pharmaceuticals Ltd)

Plot No. 215-219, G.I.D.C Industrial Area, Panoli – 394 116 Gujarat, India.

Product Registration Holder

UNIMED SDN BHD

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