

# OFLOMAC 200

## Ofloxacin tablets USP 200mg

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### What Oflomac 200 is used for

Oflomac 200 is an antibiotic that can be used to treat a variety of different infections. It is indicated for the treatment of the following infections when caused by sensitive organisms:

- Upper & lower urinary tract infections
- Lower respiratory tract infections
- Uncomplicated urethral and cervical gonorrhoea
- Non-gonococcal urethritis and cervicitis
- Skin and soft tissue infections

### How Oflomac 200 works

Ofloxacin belongs to a group of medicines called quinolone antibiotics. Ofloxacin is an antibiotic that can be used to treat a variety of different infections.

### Before you use Oflomac 200

Do not take this medicine if:

- If you are allergic to ofloxacin or any of the other ingredients of this medicine.
- 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.

Please ask your doctor about any of the conditions mentioned above.

### Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any of the following medicines:

- Medicines or dietary supplements that contain iron (for anaemia) or zinc.
- Sucralfate used for stomach ulcers.
- Antacids used for indigestion that contain magnesium or aluminium.
- Tarivid and anti-coagulants which can prolong the bleeding time
- Painkillers called non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen or diclofenac, or theophylline, used to treat asthma or chronic obstructive pulmonary disease as these could make you more prone to fits if taken with ofloxacin.
- Glibenclamide, a medicine to control your blood sugar, as the amount of these medicines in the blood may increase and have a greater effect.
- Drugs that may affect your kidney function e.g. cimetidine (used for stomach ulcers or indigestion), probenecid (used for gout) and methotrexate (used for rheumatism) as they can increase the level of ofloxacin in the blood.

If you are due to have urine tests for porphyrin (a pigment in the blood), or for opiates (strong painkillers), tell your doctor or nurse you are taking this medicine.

### Pregnancy and breast-feeding

Do not take Oflomac 200 if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. If you become pregnant while taking Oflomac 200, stop taking the tablets and contact your doctor immediately.

### How to use Oflomac 200

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- For oral use. You should swallow these tablets whole with water. Do not chew them.
- The tablets can be taken with or without food and can be divided into equal doses.
- When taking Oflomac 200, avoid strong sunlight and do not use sun lamps or solaria as your skin may be more sensitive to light.
- If you are taking iron tablets (for anaemia), antacids (for indigestion or heartburn) or sucralfate (for stomach ulcers), it is important not to take these two hours before or after taking Ofloxacin. If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor.

### When to take your medicine

- The length of your treatment will depend on how serious your infection is.
- 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.

### Dosage

**Adults (including the elderly):** The dose to be taken will depend on the location and the type of infection to be treated. For most infections the recommended dose is between 200 mg and 400 mg of Ofloxacin daily, preferably in the morning. For more severe infections your doctor may increase the dose to 400 mg of Ofloxacin twice daily (morning and evening).

The recommended doses for different infections are shown below. However, your doctor may decide you need a different dose.

- **Lower urinary tract infection**  
The recommended dose is 200 mg or 400 mg of Ofloxacin daily
- **Upper urinary tract infection**  
200–400 mg daily increasing, if necessary, to 400 mg twice a day.

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## **Ofloxacin tablets USP 200 MG**

- **Lower respiratory tract infection**  
The recommended dose is 400 mg of Ofloxacin daily. If necessary, your doctor may increase this to 400 mg twice a day.
- **Gonorrhoea of the lower organs**  
A single dose of 400 mg of Ofloxacin in the morning is usually enough. To treat other infections of the lower genital organs for which Ofloxacin is a suitable antibiotic, the dose is usually 400 mg each day.
- **Non-gonococcal urethritis and cervicitis**  
The recommended dose is 400 mg of Ofloxacin daily. If necessary, your doctor may increase this to 400 mg twice a day.
- **Skin & soft tissue infection**  
The recommended dose is 400 mg of Ofloxacin twice daily.

### **Use in children & adolescents**

Children or adolescents under 18 years of age should not take these tablets.

### **If you take more Oflomac 200 than you should**

If you take more tablets than you should you may become confused and dizzy or lose consciousness, you may have a seizure or fit, and you may feel sick. Contact your doctor or nearest hospital casualty department immediately. Take the container and any remaining tablets with you.

### **If you forget to take Oflomac 200**

If you forget to take a dose take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten tablet.

### **If you stop taking Oflomac 200**

Your doctor will tell you how long you need to take your tablets for. Do not suddenly stop taking this medicine without talking to your doctor first.

If you stop, your infection may get worse again. If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **While you are using it**

#### **- Things you must do**

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Oflomac 200.

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

#### **- Things you must not do**

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

Do not take any new medicines without consulting your doctor.

Do not give Oflomac 200 to anyone else, even if they have the same symptoms or condition as you.

#### **- Things to be careful of**

Talk to your doctor or pharmacist before taking Oflomac 200.

Taking Oflomac 200 may make you feel sleepy, dizzy or could affect your eyesight. Do not drive or use machines until you know how this medicine affects you. Drinking alcohol may make these symptoms worse.

### **Side effects**

Like all medicines Oflomac 200 may cause you some problems although not everybody gets them.

### **Digestive & 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: liver problems, such as inflammation of the liver (hepatitis) or

blockage in the bile duct, that may cause your eyes or skin to go yellow (jaundice)

### **Central nervous system**

Common: Headache, dizziness, sleep disorders, restlessness.

Rare: Feeling confused or anxious, nightmares, seeing, feeling or hearing things that are not there, depression and mental illness drowsiness, feeling of nervousness, tremor, unusual (involuntary) muscle movements, neuropathy, numbness or tingling in the hands and feet or being very sensitive to touch, numbness or weakness of the arms and legs, visual disturbances, disturbances of taste and smell.

Very rare: hearing problems or hearing loss, uncontrolled movements, unsteadiness and shaking, severe depression or mental illness. Some people who are depressed think of harming or killing themselves.

### **Cardiovascular system**

Common: Fast heartbeat & temporary decrease in blood pressure.

Rare: Pronounced drop in blood pressure

### **Haematological**

Very rare: a condition in which the amount of oxygen-carrying pigment (haemoglobin) in the blood is below normal or an illness resulting from the destruction of red blood cells with the following symptoms; feeling tired, faint, dizzy, being short of breath when exercising and having pale skin.

These may be signs of anaemia or haemolytic anaemia

### **Renal side effects**

Rare: Disturbances of kidney function.

Very rare: severe kidney problems, which may result in your kidneys stopping working. Signs may include a rash, high temperature, general aches and pains, or blood in the urine.

### **Allergic & skin side effects**

Common: Skin rash, itching

Very rare: skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with dark ring around the edge) (erythema multiforme).

A widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis).

Narrowing, blockage or leakage of blood vessels, in exceptional cases leading to severe skin reactions and death of areas of the skin.

A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens Johnson syndrome).

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## Other side effects

Rare: General feeling of discomfort, illness, or unease whose exact cause is difficult to identify.

Very rare: Excessive rise or fall in blood-sugar levels. Weakness, joint and muscle pains.

Very rare cases of long lasting ( up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

## Reporting of side effects

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [nprra.moh.gov.my](http://nprra.moh.gov.my) (Public Reporting Medicinal Problems/ Sides Effects / AEFI / Vaccine Safety).

## Storage and Disposal of Oflomac 200

Do not use your medicine after the expiry date shown on the label.

## KEEP THIS MEDICINE IN A SAFE PLACE WHERE CHILDREN CANNOT SEE OR REACH IT.

Store below 30°C in a dry place. Protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## Product Description

Oflomac 200 is a yellow colored, oval shaped biconvex film coated tablets with plain surface on both the sides..

## - Ingredients

- Active ingredient(s)

The active substances is Ofloxacin

## Inactive ingredients

Microcrystalline cellulose, Lactose, Sodium lauryl sulphate, Povidone, Sodium starch glycollate, Crospovidone, Colloidal anhydrous silica, purified talc, magnesium stearate, Isopropyl alcohol, Hypromellose, titanium dioxide, lake quinoline yellow, Polyethylene glycol, Diethyl Phthalate and purified water.

## Manufacturer and product Registration Holder

Macleods Pharmaceuticals Ltd  
Plot No. 25-27, Survey No. 366,  
Premier Ind. Estate,  
Kachigam, Daman - 396 210 (U.T.), India.

## Product Registration Holder

Zulat Pharmacy Sdn Bhd  
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