

# 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.

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**

**- 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.

**- 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, solaria).

**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)

- Abnormal heart beat
- Watery diarrhoea, which may have blood in it, possibly with stomach cramps and a high temperature
- Fits
- Hearing problems
- Liver problems that may cause your eyes or skin to go yellow (jaundice)
- Severe skin rashes (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis) which may include blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals. Symptoms may include flu-like symptoms followed by a painful red or purplish rash that spreads and blisters. If you develop any of the above you must stop taking this medicine and inform your doctor straight away
- Skin rashes caused by strong sunlight
- Feeling faint, light-headed or dizzy, due to low blood pressure
- Muscle weakness, joint and muscle pains
- Feeling weak or irritable, sweating and/or trembling. This could be due to lowering of blood sugar levels
- Feeling thirsty and passing water more often than usual. This could be due to a raise in blood sugar levels

- Swelling or discomfort in your tendons, such as in the achilles tendon
- Kidney problem. Signs may include a rash, high temperature and general aches and pains.
- Severe depression or mental illness. Some people who are depressed think of harming or killing themselves.

Rare (affects less than 1 in 1000 people)

- Numbness or tingling in the hands and feet or being very sensitive to touch

Frequency Unknown

- Abnormal fast heart rhythm
- Indigestion, flatulence (passing wind), constipation
- Fever, pain (back, chest, limbs)
- Severe abdominal pain (pancreatitis)
- Inflammation of the eye (uveitis)
- Skin redness with extensive scaling (exfoliative dermatitis)
- Loss of appetite.
- Problems with eye sight

Tell your doctor if any of the following side effects gets serious or lasts longer than a few days:

Uncommon (affects less than 1 in 100 people)

- Feeling or being sick, diarrhoea or stomach pains
- Headaches, sleeping problems, feeling dizzy or restless

Rare (affects less than 1 in 1000 people)

- Feeling confused or anxious, nightmares, seeing things that are not there, depression and mental illness, feeling drowsy, trembling, problems walking due to poor muscle control
- Changes in or loss of your sense of taste or smell
- Changes in levels of liver enzymes shown in blood tests
- A general feeling of being unwell

Very Rare (affects less than 1 in 10,000 people)

- Feeling tired, faint, and dizzy and having pale skin. These could be signs of anaemia

- You may bruise more easily than usual. This could be because of a blood problem called 'thrombocytopenia'
- Cough or shortness of breath, caused by lung inflammation

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI/ Vaccine Safety)

### 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. 216-219, G.I.D.C Industrial Area, Panoli – 394 116 Gujarat, India.

### Product Registration Holder

**UNIMED SDN BHD**  
53, Jalan Tembaga 5/2B  
Bandar Sri Damansara  
52200, Kuala Lumpur  
Malaysia

### Date of revision

7/12/2017

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NPRA(R4/1061217/00345)