Patient package insert according to Pharmacists' Regulations (Preparations) - 1986

This medicine can be sold with a physician's prescription only

Oflodex, caplets

Each caplet contains ofloxacin 200 mg

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 – "Important information about some of the ingredients of this medicine".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if you think that their illness is to the same as yours.

1. What is the medicine intended for?

The medicine is intended for treatment of bacterial infections caused by bacteria susceptible to ofloxacin: respiratory tract infections, pneumonia, ear, nose or throat infections , infections of the kidney, urinary tract and genital organs (including gonorrhea, a sexually transmitted disease), gastrointestinal infections including bacterial colitis, soft tissue and skin infections, bone and joint infections.

Therapeutic group:
Antibiotic medicine belonging to the fluoroquinolone group.

2. Before using the medicine

Do not use the medicine if:
- You are hypersensitive (allergic) to the active ingredient (ofloxacin), or to any of the other ingredients this medicine contains (see section 6).
- You have suffered in the past from an allergic reaction to an antibiotic of the quinolone group. If you have suffered in the past from an allergic reaction to any type of antibiotic, consult with your doctor before taking the medicine.
- You have suffered in the past from tendinitis after taking antibiotics from the fluoroquinolone group.
- You suffer from epilepsy or you have suffered in the past from seizures or convulsion.
- You suffer from glucose-6-phosphate dehydrogenase deficiency (an inherited disease that affects the red blood cells). Upon treatment with the medicine, the red blood cells may break down, causing anemia or jaundice.
- You are pregnant or breastfeeding.
- You are under 18 years of age, or you are over 18 years of age, but think you are still in the growth stage.
- You suffer from infection by methicillin-resistant Staphylococcus aureus (MRSA)
- You suffer from visual disorders.

Special warnings regarding the use of this medicine:
Heart problems Take cautionary measures when using this medicine if you were born with or if you have a family history of prolonged QT interval (seen on ECG, recording of the electrical activity of the heart), have salt imbalance in the blood (especially a low level of potassium or magnesium in the blood), you have a very slow heart rhythm (called bradycardia), you have a weak heart (heart failure), you have had a heart attack in the past (myocardial infarction), you are a woman or an elderly man or you take other medicines which cause abnormal ECG changes (see section 2- "Drug interactions").

Before treatment with Oflodex, tell your doctor if:
- You suffer or have suffered in the past from mental illness.
- You suffer from liver or kidney problems. Make certain that you have informed your doctor about any liver or kidney problem before starting to use the medicine, since you may be required to lower the dosage.
- You suffer from a disease of the nervous system called severe muscle weakness (myasthenia gravis), a disease in which the muscles are weak and tire easily.
- You are elderly or you were given corticosteroids (used for the treatment of asthma and other chronic lung diseases), since they may increase the risk of swelling and pain in the tendons.
- You have diabetes.
- You are taking a medicine called Fenbufen or other medicines from the NSAIDs group, antagonists of vitamin K.
- You take theophylline.
- You were diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysem).
- You have suffered in the past from aortic dissection (tear in the aorta wall).
- You were diagnosed with leaking heart valves (heart valve regurgitation).
- You have a family history of aortic aneurysm, aortic dissection, congenital heart valve disease, or other risks factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, vascular Ehlers-Danlos syndrome, Turner's syndrome, Sjörgen's syndrome [inflammatory autoimmune disease], or a vascular disorders such as Takayasu's arteritis, giant cell arteritis, Behcet's disease, hypertension, or known atherosclerosis and rheumatoid arthritis [a disease of the joints]), or endocarditis [an infection of the heart]).

Before taking the medicine:
Do not take antibiotic drugs from the fluoroquinolone/ quinolone family, including ofloxacin, if you have suffered in the past from severe side effects during the use of quinolones or fluoroquinolones. In this case, inform your doctor as soon as possible.
- If you feel sudden severe abdominal, chest or back pain, which may be symptoms of aortic aneurysm or dissection, go immediately to the emergency room. Your risk is increased if you are treated with systemic corticosteroids.
- If you start experiencing rapid attacks of shortness of breath, especially when you lie down flat, or if you notice swelling of your ankles, feet and abdomen, or the appearance of new heart palpitations (feeling of rapid or irregular heartbeat), inform the doctor immediately.

During treatment with the medicine:
- You may experience a sudden severe allergic reaction (anaphylactic reaction/shock). Even after having taken the first dose, there is a chance that you may experience a sudden severe allergic reaction with the following symptoms: pressure in the chest, feeling of dizziness, feeling weak or faint, or feeling dizzy while standing. If this occurs, stop taking the medicine and contact your doctor immediately.
- You may experience a psychiatric reaction after taking ofloxacin for the first time. If you suffer from depression or psychosis, your symptoms may become worse when taking ofloxacin. If this occurs, stop taking the medicine and contact your doctor immediately.
- You may experience symptoms of liver problems, such as loss of appetite,yellowing of the skin and whites of the eyes, dark urine, itching or abdominal tenderness. Stop taking the medicine immediately.
- Diarrhea may develop during treatment with antibiotics, including ofloxacin, or weeks after you stop taking treatment with them. If the diarrhea becomes severe or continuous, or if you detect that the stool contains blood or mucous, tell your doctor immediately. Treatment with the medicine must stop immediately, since this may be life-threatening. Pain and swelling of the joints and tendon inflammation or a rupture may occur rarely. You are at much higher risk if you are elderly (over 60 years of age), have received an organ transplant, have kidney problems, or are treated with corticosteroids. Tendon inflammation and ruptures may occur over the course of the first 48 hours from the start of treatment and even after a number of months after you stop taking the medicine; with the appearance of the first sign of tendon pain or inflammation (for example in the ankle, wrist, shoulder or knee), stop taking the medicine, contact your doctor and let the painful area rest. Avoid unnecessary physical activity, since it may increase the risk of a tendon rupture.
- Rarely, you may experience symptoms of nerve impairment (neuropathy) such as pain, burning sensation, tingling, numbness and/or weakness, especially in the feet and legs or hands and arms. If this occurs, stop taking the medicine and inform your doctor immediately in order to avoid the possibility of developing an irreversible medical condition.
- Tell your doctor if it is known that you or a relative have a deficiency of the enzyme glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anemia with the use of ofloxacin.
- Do not expose yourself to prolonged periods of strong sunlight while taking the medicine. Use sunscreen if you cannot avoid strong sunlight.
- Do not use tanning or solarium lights.
- You may be more sensitive to other bacterial infections.
- Inform your doctor that you are taking this medicine if you are supposed to undergo any medical tests, since the medicine may affect the results.
- You may experience skin reaction problems such as Stevens-Johnson syndrome, a rare and severe disorder of the skin and the mucous membrane, or toxic necrolysis of the upper skin layer, a condition in which there is a separation of this layer from the lower skin layers.

Quinolone antibiotics may cause an increase in the blood sugar levels above the normal levels (hyperglycemia), or a decrease in the blood sugar levels below the normal levels. In severe cases, the condition may lead to loss of consciousness (hypoglycemic coma) (see section 4 – "Side effects"). This is important to people with diabetes. If you suffer from diabetes, your blood sugar level must be carefully monitored.

Prolonged, disabling serious side effects which may be irreversible
Antibacterial medicines of the fluoroquinolone/ quinolone group, including ofloxacin, have been associated with very rare but serious side effects, some of which continue along time (for months or years), disabling or may be irreversible. These include pain in the tendon, in the muscle, and in the joint of the upper and lower extremities, difficulty walking, abnormal sensitivity such as a sensation of "pins and needles", tingling, tickling, numbness, or burning sensation (paresthesia), sensory disorders including impairment of vision, taste, smell and hearing, depression, memory impairment, severe fatigue and severe sleeping problems.

If you feel one of these side effects after taking the medicine, contact your doctor immediately before continuing treatment. You and your doctor will decide whether to continue treatment, as well as the use of antibiotics from another family.

Tests and follow-up:
- The doctor may want you toperform blood tests for follow-up, if you take ofloxacin for more than two weeks.

Drug interactions:
If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Especially if you are taking:
- Anticoagulants (tablets that prevent blood clotting, such as warfarin), as bleeding time may be longer.
- Antacids, sucralfate, Didanosine, aluminum, iron, magnesium, or zinc preparations (see section 3 – "How to use the medicine").
- Medicines for control of blood sugar levels (such as Glibenclamide), since concentrations of these medicines in the blood may increase and they will have a greater effect.
- Theophylline or non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen, diclofenac or Fenbufen, as some people suffer from seizures when they take these drugs with ofloxacin.
- Medicines that may affect kidney function (such as cimetidine, furosemide, probenecid or methotrexate), as these medicines may sometimes increase the levels of ofloxacin in the blood.

You must tell your doctor if you take other medicines that may alter the heart rhythm: medicines belonging to the anti-arrhythmic group (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, Ibutilide, procainamide), tricyclic antidepressants e.g. amitriptyline, clomipramine, certain antibiotics (that belong to the macrolide group e.g. erythromycin or azithromycin), some antipsychotic drugs (such as olanzapine, quetiapine).

Pregnancy breastfeeding and fertility:
Do not use Oflodex if you are pregnant or breastfeeding.
There is limited information on the use of ofloxacin in pregnant women.
Ofloxacin is known to be excreted in breast milk in small quantities.

Driving and use of machinery:
The medicine may make you feel sleepy, dizzy or may affect your vision, which may affect your ability to concentrate. If you are affected, do not drive or operate machines.

Important information about some of the ingredients of this medicine:
This medicine contains less than 1 mmol of sodium (23 mg) per caplet, that is to say essentially "sodium-free"

3. How to use this medicine?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.
The dosage and manner of treatment will be determined by the doctor only.
Do not take the medicine more than 8 weeks continuously.
Patients with liver disease and patients with impaired renal function will have their dosage adjusted by the doctor depending on their condition.
Do not exceed the recommended dose.

Children and adolescents:
Oflodex should not be given to children or growing adolescents.

Taking the medicine:
Swallow the caplets whole with a full glass of water. The caplet may be halved at the score-line into two equal doses. There is no information on chewing or crushing.

Taking the medicine in combination with antacids, sucralfate, aluminum, iron, magnesium or zinc preparations:
You must wait for a period of at least two hours between taking ofloxacin and taking each of the above-mentioned medicines, otherwise, the medicine may not work properly.

If you have accidentally taken a higher dosage
If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the leaflet, the remaining caplets and the medicine package to the hospital or the doctor, in order to know which caplets were consumed.

An overdose may cause dizziness, confusion, seizures, loss of consciousness, QT interval prolongation, feeling the presence of objects that do not exist, involuntary shaking of the body and extremities, nausea, and severe stomach problems.

If you forgot to take the medicine:
If you forgot to take a caplet, take one as soon as you remember, unless it is nearly time to take the next caplet. Do not take a double dose in order to compensate for the forgotten dose.

Continue with the treatment as recommended by the doctor.

If you stop taking the medicine: Even if your health condition improves, do not stop taking this medicine without consulting your doctor. If you fail to do this, the symptoms may return.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. Side effects

Like any medicine, the use of **Oflodex** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
- **Stop taking this medicine and refer to the doctor or to a hospital emergency room immediately with the appearance of:** An allergic reaction, sometimes even after taking the first dose, which may include swelling of the lips, face or neck and leading to severe difficulty breathing, skin rash or hives, fast heart rate, low blood pressure, fever, burning of the eyes, throat irritation, coughing, wheezing, shock or blood disorders.
- Skin problems that comes from an allergic reaction or infection (drug eruption), visible accumulation of fluid within or beneath the skin (vesiculobullous rash), skin rash caused by sunlight (photosensitivity reaction), inflammatory skin eruption (erythema multiforme).
- Inflammation and ulceration of the mouth, eyes, gut and genitals. These may be due to Stevens-Johnson syndrome or toxic epidermal necrolysis, which are serious diseases.
- Tendon discomfort, including inflammation or rupture, especially if you are elderly or also take corticosteroids e.g. prednisolone.
- Spasms, agitation, nightmares, anxiety, depression, hallucinations, feeling of wanting to harm yourself or disturbances of the mind, confusion, ringing in the ears, unsteadiness, shaking, disturbances of sensation, numbness, sensation of "pins and needles", blurred, double or odd color problems, problems with or loss of hearing, sense of taste and smell.
- Diarrhea containing blood.
- Inflammation of the liver which may be severe. Loss of appetite, yellowing of the skin and eyes, dark-colored urine, irritation or tenderness of the abdomen. All these may be signs of liver problems which may include fatal liver failure.

The following side effects were reported at the relative frequencies as described below:
Uncommon side-effects (effects that appear in 1-10 out of 1,000 users):
- Fungal infection, resistance of infection causing organisms to this treatment, (you may fail to respond to treatment).
- Headache, dizziness, sleep disturbances, and restlessness.
- Eye irritation, sensation of spinning (vertigo), cough, nose inflammation.
- Nausea or vomiting, diarrhea, abdominal pain.
- Skin rash, itching.

Rare side-effects (effects that appear in 1-10 out of 10,000 users):
- Loss of appetite.
- Sleepiness.
- Faster heart rate (tachycardia).
- Low blood pressure.
- Difficulty breathing or wheezing, shortness of breath.
- Bowel inflammation which may cause bleeding.
- Liver function impairment with abnormal blood test results.
- Urticaria (hives).
- Menstrual disturbances (such as hot flashes), excessive sweating, pustular rash.
- Increased creatinine levels in the blood.
- Delirium (acute state of confusion).

Very rare side-effects (effects that appear in less than 1 out of 10,000 users):
- Anemia (reduction in the number of red blood cells causing pale or yellow skin, unusual tiredness or weakness.
- Other blood disorders when the numbers of different types of cells in the blood may decrease. Symptoms can include fever, chills, sore throat, ulcers in the mouth and throat, unusual bleeding, or unexplained bruises.
- Abnormal dreams or mental illnesses.
- Impairments of voluntary movements i.e. tremor, tics. Changes in muscle tone, slow movement.
- An allergic reaction in the eye or the skin around the eye.
- Failure of blood circulation in the body.
- Flushing.
- Rash-like bruises.
- Inflammation of the blood vessels, frequently with skin rash.
- Muscle weakness, joint and muscle pain.
- Effect on kidney function, which may lead to kidney insufficiency.
- Unbalanced walking.

Side effects with unknown frequency (effects for which a frequency has not yet been determined):
- Severe decrease in the number of white blood cells which raise the likelihood of infections.
- Loss of consciousness as a result of a severe decrease in the blood sugar levels (hypoglycemic coma). See section 2 – "During treatment with the medicine".
- Abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called "prolongation QT interval", seen in an ECG, recording of the electrical activity of the heart).
- Inflammation of the lungs which causes breathlessness, cough, and high fever (allergic pneumonia).
- Severe shortness of breath
- Acute generalized exanthematous pustulosis (a swollen red area with numerous small pustules).
- Pain or muscle weakness, abnormal muscle breakdown, which may lead to kidney problems.
- Tear (partial or complete) of the muscle.
- Inflammation of the kidneys which may cause swollen ankles or
- High blood pressure. The medicine may trigger an attack of porphyria in susceptible patients.
- Increase in blood sugar levels (especially in diabetic patients).
- Nervousness..
- Involuntary shaking of the body or uncontrolled movement of the upper body or the lower extremities.
- Loss of taste function of the tongue.
- Temporary loss of consciousness caused by a fall in blood pressure.
- Fever.
- Painful, difficult, or disturbed digestion,, which may be accompanied by symptoms such as nausea and vomiting, heartburn, bloating and abdominal discomfort, accumulation of gas in the gastrointestinal system, pain when having a bowel movement, inflammation of the pancreas.
- Inflammation of the mouth and lips.
- Inflammation and stiffness of the joints.
- Loss or lack of physical strength including pain in the back, chest and extremities.
- Bone marrow failure which may lead to pancytopenia (a medical condition in which there is a decrease in the number of red and white blood cells as well as plateles).
- Eye infection (uveitis).
- Extensive skin redness (exfoliative dermatitis).

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

In patients who take fluoroquinolones, cases were reported of enlargement or weakening of the aortic wall or partial tear in the aortic wall (aneurysm or dissection), which may lead to a complete rupture and may be fatal, and cases of leaking heart valves. See section 2.

If a side effect appears, if one of the side effects worsensor if you suffer from side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעת לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health (www.health.gov.il) directing to the online form of adverse events reporting, or via the following link: https://sideeffects.health.gov.il/

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that same month.

Storage conditions: store below 25°C.

6. Additional Information

In addition to the active ingredient, this medicine also contains:
Microcrystalline cellulose, hydroxypropyl cellulose, sodium starch glycolate, hypromellose, magnesium stearate, titanium dioxide, macrogol.

What the medicine looks like and what the package contain:
White-coated caplets with a score-line on both sides. Approved package sizes: 10 or 20 caplets.
Not all package sizes may be marketed.

Revised in July 2022 according to MOH guidelines.

Drug registration number in the National Drug Registry of the Ministry of Health:
121-99-30179-00

Manufacturer and registration holder:
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