

## 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 gonorrhoea, 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 tendonitis 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.

#### Before taking the medicine:

Do not take antibiotic drugs from the fluoroquinolone/quinolone group, 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.
- Rarely, you may experience symptoms of nerve impairment (neuropathy) such as taking the medicine, contact your doctor 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.

#### 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.

- 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.
- You were diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- 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 risk 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]).

in the ankle, wrist, shoulder or knee), burning sensation (paresthesia), sensory stop taking the medicine, contact your doctor and let the painful area rest. Avoid taste, smell and hearing, depression, memory unnecessary physical activity, since it may impairment, severe fatigue and severe increase the risk of a tendon rupture.

- 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.
- Rarely, you may experience symptoms of nerve impairment (neuropathy) such as taking the medicine, contact your doctor 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.

#### Tests and follow-up:

- The doctor may want you to perform 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 (e.g. 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, lbutilide, procainamide), tricyclic antidepressants e.g. amitriptyline, clomipramine, certain antibiotics (that belong to the macrolide group e.g. erythromycin or azithromycin), some antipsychotic drugs (e.g. olanzapine, quetiapine).

#### 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

Ofloxacin is known to be excreted in breast milk in small quantities.

#### Driving and using 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 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.

**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

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irregular heart rhythm, alteration of the heart rhythm (called “prolongation QT interval”, 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 worsens or 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 תופעות לוואי ועקב” 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 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 August 2021 according to Ministry of Health Guidelines.

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

**Manufacturer and registration holder:**

**Dexcel® Ltd.**

1 Dexcel St., Or Akiva 3060000, Israel

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.

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