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

section 2 - "Important information about some medicine if you were born with or if you have of the ingredients of this medicine".

The medicine is intended for treatment doctor if:

Therapeutic group:

Antibiotic medicine belonging to the fluoroauinolone

- ingredient (ofloxacin), or to any of the other | You have diabetes. ingredients this medicine contains (see | section 6).
- You have suffered in the past from an allergic reaction to an antibiotic of the guinolone 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.
- 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 suffer from visual disorders.

- 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 methicillinresistant Staphylococcus aureus (MRSA)

medicine: Inactive ingredients and allergens in the medicine Heart problems - see section 6 "Additional information" and in Take cautionary measures when using this

(seen on ECG, recording of the electrical Read this entire leaflet carefully before using activity of the heart), have salt imbalance in this medicine. This leaflet contains concise the blood (especially a low level of potassium information about the medicine. If you have any or magnesium in the blood) you have a very further questions, please refer to your doctor or slow heart rhythm (called 'bradycardia) you have a weak heart (heart failure), you have

This medicine has been prescribed to treat your had a heart attack in the past 'myocardial illness. Do not pass it on to others. It may harm infarction), you are a woman or an elderly them, even if you think that their illness is to the man or you take other medicines which cause

1. What is the medicine intended for?

of bacterial infections caused by bacteria • You suffer or have suffered in the past from susceptible to ofloxacin; respiratory tract infections. pneumonia, ear, nose or throat • You suffer from liver or kidney problems. infections, infections of the kidney, urinary tract and genital organs (including gonorrhea. a sexually transmitted disease), gastrointestinal infections including bacterial colitis, soft tissue

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active
- You take theophylline. or "bulge" of a large blood vessel (aortic You have suffered in the past from aneurvsem)
 - You have suffered in the past from aortic
 - dissection (tear in the aorta wall). You were diagnosed with leaking heart valves (heart valve regurgitation).

interactions").

mental illness

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. Ehlers-Danlos syndrome. Turner's syndrome. Siörgen's syndrome [inflammatory autoimmune disease], or a vascular disorders such as Takavasu's arteritis, giant cell arteritis. Behcet's disease. hypertension, or known atherosclerosis and rheumatoid arthritis [a disease of the joints]).

Special warnings regarding the use of this

a family history of prolonged QT interval

doctor about any liver or kidney problem

before starting to use the medicine, since

you may be required to lower the dosage.

system called severe muscle weakness

(myasthenia gravis), a disease in which the

corticosteroids (used for the treatment of

asthma and other chronic lung diseases).

since they may increase the risk of swelling

You are taking a medicine called Fenbufen

or other medicines from the NSAIDs group.

or endocarditis (an infection of the heart)).

You are elderly or you we're given

muscles are weak and tire easily

and pain in the tendons

antagonists of vitamin K.

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 auinolones or fluoroauinolones. In this case. inform your doctor as soon as possible.

Before taking the medicine:

 If you feel sudden severe abdominal, chest 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 appearance of new heart palpitations (feeling of rapid or irregular heartbeat), inform the doctor immediately abnormal ECG changes (see section 2- "Drug During treatment with the medicine:

reaction (anaphylactic reaction/shock). Even Before treatment with Oflodex, tell your after having taken the first dose, there is a chance that you may experience a sudden severe alleraic reaction with the following • Do not use tanning or solarium lights. Make certain that you have informed your

symptoms: pressure in the chest, feeling of • You may be more sensitive to other bacterial may be longer. dizziness, feeling weak or faint, or feeling taking the medicine and contact your doctor

immediately. and skin infections, bone and joint infections. • You suffer from a disease of the nervous • You may experience a psychiatric reaction vou 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

contains blood or mucous, tell your doctor carefully monitored. must stop immediately, since this may be which may be irreversible

life-threatening. months after you stop taking the medicine: with the appearance of the first sign of tendon pain or inflammation (for example

increase the risk of a tendon rupture. sleeping problems.

taking the medicine and inform your doctor antibiotics from another group. immediately in order to avoid the possibility of Tests and follow-up:

your ankles, feet and abdomen, or the • Tell your doctor if it is known that you or tests for follow-up, if you take offoxacin for pharmacist if you are not sure about the dosage alarmed when reading the list of side effects. • Low blood pressure. a relative have a deficiency of the enzyme more than two weeks. glucose-6-phosphate dehydrogenase **Drug interactions**: anemia with the use of ofloxacin

medicine. Use sunscreen if you cannot Especially if you are taking: avoid strong sunlight

infections dizzv while standing. If this occurs, stop • Inform your doctor that you are taking this medicine if you are supposed to undergo

affect the results. after taking ofloxacin for the first time. If • You may experience skin reaction problems and severe disorder of the skin and the

lower skin lavers problems, such as loss of appetite, yellowing Ouinolone antibiotics may cause an increase drugs with ofloxacin. Stop taking the medicine immediately. blood sugar levels below the normal levels. In or methotrexate), as these medicines may the medicine may not work properly. You were diagnosed with an enlargement with antibiotics, including ofloxacin, or of consciousness (hypoglycemic coma) (see in the blood.

immediately. Treatment with the medicine prolonged, disabling serious side effects hydroquinidine, disopyramide, amiodarone, remaining caplets and the medicine package sensation, numbness, sensation of "pins • Muscle weakness, joint and muscle pain.

Antibacterial medicines of the fluoroguinolone/ tricyclic antidepressants e.g. amitriptyline, which caplets were consumed. (over 60 years of age), have received an time (for months or years), disabling or may be olanzapine, quetiapine). organ transplant, have kidney problems, irreversible. These include pain in the tendon, Pregnancy breastfeeding and fertility: inflammation and ruptures may occur over lower extremities, difficulty walking, abnormal breastfeeding. the course of the first 48 hours from the start sensitivity such as a sensation of "pins and There is limited information on the of treatment and even after a number of needles", tingling, tickling, numbness, or ofloxacin in pregnant women.

in the ankle, wrist, shoulder or knee), burning sensation (paresthesia), sensory The medicine may make you feel sleepy, dizzy health condition improves, do not stop taking may fall to respond to treatment. stop taking the medicine, contact your disorders including impairment of vision or may affect your vision, which may may this medicine without consulting your doctor. • Headache. dizziness. sleep disturbances. doctor and let the painful area rest. Avoid taste, smell and hearing, depression, memory affect your ability to concentrate. If you are if you fail to do this, the symptoms may return. unnecessary physical activity, since it may impairment, severe fatioue and severe affected, do not drive or operate machines. Do not take medicines in the dark! Check • Eve irritation, sensation of spinning (vertigo).

or back pain, which may be symptoms • Rarely, you may experience symptoms of If you feel one of these side effects after ingredients of this medicine: nerve impairment (neuropathy) such as taking the medicine contact your doctor This medicine contains less than 1 mmol if you have any further questions on the pain and/or weakness, especially in the feet and You and your doctor will decide whether essentially "sodium-free" legs or hands and arms. If this occurs, stop to continue treatment, as well as the use of

(G6PD), since you may experience a risk of If you are taking, have recently taken or determined by the doctor only. might take other medicines, including Do not take the medicine more than 8 weeks immediately with the appearance of: · You may experience a sudden severe allergic • Do not expose yourself to prolonged non-prescription medicines and nutritional continuously

clotting, such as warfarin), as bleeding time condition.

 Antacids sucralfate Didanosine aluminum iron, magnesium, or zinc preparations (see Oflodex should not be given to children or disorders. section 3 - "How to use the medicine").

any medical tests, since the medicine may • Medicines for control of blood sugar Taking the medicine: levels (such as Glibenclamide), since Swallow the caplets whole with a full glass of concentrations of these medicines in the water. greater effect

mucous membrane, or toxic necrolysis of • Theophylline or non-steroidal anti- chewing or crushing. suffer from seizures when they take these magnesium or zinc preparations:

or are treated with corticosteroids. Tendon in the muscle, and in the joint of the upper and **Do not use Oflodex if you are pregnant or** stomach problems.

Office of the organization of the expression of milk in small quantities.

Driving and using machinery:

Important information about some of the the label and the dose each time you take couch, nose inflammation.

pain, burning sensation, tingling, numbness immediately before continuing treatment of sodium (23 mg) per caplet, that is to say use of this medicine, consult the doctor or • Skin rash, itching. nharmacist.

3. How to use this medicine?

Always use this medicine according to the Like any medicine, the use of Oflodex may . Sleepiness developing an irreversible medical condition. • The doctor may want you to perform blood doctor's instructions. Check with the doctor or cause side effects in some users. Do not be • Faster heart rate (tachycardia). and the manner of treatment with the medicine. You may not suffer from any of them. The dosage and manner of treatment will be **Stop taking this medicine and refer to the** of breath.

impaired renal function will have their dosage swelling of the lips, face or neck and leading • Urticaria (hives). • Anticoagulants (tablets that prevent blood adjusted by the doctor depending on their to severe difficulty breathing, skin rash or • Menstrual disturbances (such as hot diabetic patients).

Do not exceed the recommended dose. Children and adolescents:

growing adolescents.

such as Stevens-Johnson syndrome, a rare blood may increase and they will have a The caplet may be halved at the score-line into two equal doses. There is no information on

the upper skin layer, a condition in which inflammatory drugs (NSAIDs) e.g. ibuprofen. Taking the medicine in combination with there is a separation of this layer from the diclofenac or Fenburen, as some people antacids, sucralfate, aluminum, iron, eyes, gut and genitals. These may be due bruises.

of the skin and whites of the eyes, dark in the blood sugar levels above the normal • Medicines that may affect kidney function between taking offoxacin and taking each of diseases. urine, itching or abdominal tenderness levels (hyperalycemia), or a decrease in the (e.g. cimetidine, furosemide, probenecid the above-mentioned medicines, otherwise, • Tendon discomfort, including inflammation movement

• Diarrhea may develop during treatment severe cases, the condition may lead to loss sometimes increase the levels of ofloxacin if you have accidentally taken a higher also take corticosteroids e.g. prednisolone. around the eye. dosage

weeks after you stop taking treatment with section 4 - "Side effects"]. This is important you must tell your doctor if you take If you have taken an overdose or if a child depression, hallucinations, feeling of • Flushing aneurysm or large vessel peripheral them. If the diarrhea becomes severe or to people with diabetes. If you suffer from other medicines that may alter the heart has accidentally swallowed the medicine, wanting to harm yourself or disturbances • Rash-like bruises continuous, or if you detect that the stool diabetes, your blood sugar level must be rhythm; medicines belonging to the proceed immediately to a doctor or a hospital of the mind, confusion, ringing in the ears, • Inflammation of the blood anti-arrhythmic group (e.g., quinidine emergency room and bring the leaflet, the unsteadiness, shaking, disturbances of frequently with skin rash. sotalol. dofetilide. Ibutilide. procainamide), to the hospital or the doctor, in order to know and needles", blurred, double or odd color • Effect on kidney function, which may lead to dermatitis).

Pain and swelling of the joints and tendon quinolone group, including ofloxacin, have clomioramine, certain antibiotics (that belong An overdose may cause dizziness, confusion, inflammation or a rupture may occur rarely, been associated with very rare but serious to the macrolide group e.g. erythromycin or seizures, loss of consciousness, QT interval • Diarrhea containing blood. You are at much higher risk if you are elderly side effects, some of which continue along azithromycin), some antiposychotic drugs (e.g., prolongation, feeling the presence of objects • Inflammation of the liver which may be (effects for which a frequency has not yet been pain, pain in the extremities, difficulty walking, Drug Registry of the Ministry of Health: that do not exist, involuntary shaking of the severe. Loss of appetite, vellowing of the determined): body and extremities, nausea, and severe skin and eves dark-colored urine, irritation • Severe decrease in the number of white "pins and needles", tingling, burning

If you forgot to take the medicine:

of If you forgot to take a caplet, take one as soon include fatal liver failure. dose in order to compensate for the forgotten **below**:

by the doctor.

If you stop taking the medicine. Even if your causing organisms to this treatment (you

4. Side effects

doctor or to a hospital emergency room • Bowel inflammation which may

periods of strong sunlight while taking the supplements, tell the doctor or pharmacist. Patients with liver disease and patients with taking the first dose, which may include blood test results. fever, burning of the eyes, throat irritation. • Increased creatinine levels in the blood.

• Skin problems that comes from an allergic • Anemia (reduction in the number of red • Loss of taste function of the tongue. accumulation of fluid within or beneath the unusual tiredness or weakness. by sunlight (photosensitivity reaction). inflammatory skin eruption (erythema decrease, Symptoms can include fever, multiforme)

 Inflammation and ulceration of the mouth. to Stevens-Johnson syndrome or toxic • Abnormal dreams or mental illnesses.

• Spasms agitation nightmares anxiety • Failure of blood circulation in the body problems, problems with or loss of hearing, kidney insufficiency.

sense of taste and smell.

may be signs of liver problems which may infections.

as you remember, unless it is nearly time to The following side effects were reported take the next caplet. Do not take a double at the relative frequencies as described

Uncommon side-effects (effects that appear • Abnormal fast heart rhythm, life-threatening

Fungal infection, resistance of infection

a medicine. Wear glasses if you need them. • Nausea or vomiting, diarrhea, abdominal breathlessness, cough, and high fever the agric wall or partial tear in the agric wall

Rare side-effects (effects that appear in 1-10 • Acute

out of 10 000 users). Loss of appetite.

Difficulty breathing or wheezing shortness
Tear (partial or complete) of the muscle.

bleeding

hives, fast heart rate, low blood pressure. flashes), excessive sweating, pustular rash. • Nervousness,

ess than 1 out of 10,000 users):

reaction or infection (drug eruption), visible blood cells causing pale or vellow skin. • Temporary loss of consciousness caused by by your doctor. skin (vesiculobullous rash) skin rash caused • Other blood disorders when the numbers • Fever.

chills, sore throat, ulcers in the mouth and throat, unusual bleeding, or unexplained

tremor, tics. Changes in muscle tone, slow • Inflammation of the mouth and lips.

or rupture, especially if you are elderly or • An alleroic reaction in the eye or the skin • Loss or lack of physical strength including dioxide, macrogol.

Unbalanced walking.

severe decrease in the blood sugar levels vision and sense of taste and smell have been (hypoglycemic coma). See section 2 -"During treatment with the medicine".

irregular heart rhythm alteration of the heart associated with intake of antibiotics of the rhythm (called "prolongation QT interval", guinolone or fluoroguinolone group, in some seen in an ECG, recording of the electrical cases irrespective of pre-existing risk factors. activity of the heart)

 Inflammation of the lungs which causes were reported of enlargement or weakening of (allergic pneumonia).

Severe shortness of breath

numerous small pustules)

problems.

pressure • An allergic reaction, sometimes even after • Liver function impairment with abnormal • The medicine may trigger an attack of events reporting, or via the following link:

porphyria in susceptible patients. Increase in blood sugar levels (especially in

or the lower extremities

a fall in blood pressure.

which may be accompanied by symptoms Storage conditions: store below 25°C. such as nausea and vomiting, heartburn, bloating and abdominal discomfort 6. Additional Information system, pain when having a bowel medicine also contains:

· Inflammation and stiffness of the joints.

 Bone marrow failure which may lead to package contain: pancytopenia (a medical condition in which White-coated caplets with a score-line on

white blood cells as well as plateles). Eve infection (uveitis). Extensive skin redness (exfoliative Revised in August 2021 according to Ministry

Very rare cases of long lasting (up to months of Health Guidelines. or years) or permanent side effects, such as: Side effects with unknown frequency tendon inflammations, tendon rupture, joint Drug registration number in the National abnormal sensations such as a sensation of 121-99-30179-00 or tenderness of the abdomen. All these blood cells which raise the likelihood of sensation, numbness or pain (neuropathy), Manufacturer and registration holder depression, fatique, sleep disorders, memory • Loss of consciousness as a result of a impairment as well as impairment of hearing, Dexcel® Ltd.

In patients who take fluoroguinolones, cases (aneurysm or dissection), which may lead to a complete rupture and may be fatal, and cases generalized exanthematous of leaking heart valves. See section 2.

pustulosis (a swollen red area with If a side effect appears, if one of the side effects worsens or if you suffer from side Pain or muscle weakness, abnormal muscle effect which is not mentioned in this leaflet breakdown which may lead to kidney consult the doctor.

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעות לוואי עקב" Inflammation of the kidneys which may טיפול תרופתי that can be found on the home cause swollen ankles or high blood page of the Ministry of Health (www.health. gov il) directing to the online form of adverse https://sideeffects.health.gov.il/

5. How to store the medicine?

Avoid poisoning! This medicine and any other Involuntary shaking of the body or medicine must be stored in a closed place coughing, wheezing, shock or blood Very rare side-effects (effects that appear in uncontrolled movement of the upper body out of the reach and sight of children and/ or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so

> Do not use the medicine after the expire date stated on the package. The expiry date of different types of cells in the blood may . Painful, difficult, or disturbed digestion. refers to the last day of that same month.

accumulation of gas in the gastrointestinal In addition to the active ingredient, this

You must wait for a period of at least two hours epidermal necrolysis, which are serious. Impairments of voluntary movements i.e. movement, inflammation of the pancreas. Microcrystalline cellulose. hydroxypropyl cellulose, sodium starch alvcolate hypromellose, magnesium stearate, titanium

pain in the back, chest and extremities. What the medicine looks like and what the

there is a decrease in the number of red and both sides. Approved package sizes: 10 or 20 caplets.

Not all package sizes may be marketed.

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