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

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

# Ciprodex® 500, Caplets reaction in the past when taking a quinolone or

Each caplet contains ciprofloxacin as your doctor as soon as possible hydrochloride at a dose of 500 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 the medicine". conditions, you have a history of seizures.

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their illness is similar.

# 1. What is the medicine used for?

Ciprodex is used in adults to treat the following bacterial infections

- respiratory tract infections
- long lasting or recurring ear or sinus infections. urinary tract infections
- genital tract infections in men and women
- gastro-intestinal tract infections and intraabdominal infections
- skin and soft tissue infections
- bone and joint infections
- to prevent infections due to the bacterium Neisseria meningitidis
- anthrax inhalation

Treatment for children and adolescents, under specialist medical supervision, to treat the following bacterial infections: · lung and bronchial infections in children and

- adolescents suffering from cystic fibrosis complicated urinary tract infections including
- infections that have reached the kidneys (pvelonephritis).
- anthrax inhalation exposure.
- Ciprodex may also be used to treat other specific severe infections in children and adolescents when your doctor considered this necessary. Therapeutic group: antibiotic of the

fluoroquinolone group.

### 2. Before using the medicine Do not use the medicine if:

 You are hypersensitive (allergic) to the active ingredient (ciprofloxacin), to other medicines of the guinolone group or to one of the additional ingredients the medicine contains (see section 6) You are taking tizanidine (also see section "Drug") interactions").

#### Special warning regarding the use of this medicine:

Before treatment with Ciprodex

antibacterial medicines, including Ciprodex, consult your doctor. if you have experienced any serious adverse • In children under the age of 18 there is a higher

your treatment may need to be adjusted

you have been diagnosed with an enlargement or

aortic dissection, congenital heart valve disease

Siögren's syndrome fautoimmune inflammatory

diseasel or vascular disorders such as Takavasu

in abnormal ECG changes (see section: "Drug

you suffer from impaired liver function.

or large vessel peripheral aneurysm).

valve (heart valve regurgitation).

aortic dissection (a tear in the aorta wall).

exacerhated

[heart infection])

interactions").

 Before treatment with Ciprodex, tell the Ciprodex needs to be stopped. physician if:

vou have ever had kidney problems because reaction/shock, angioedema) which may be fatal. Even with the first dose, there is a small chance you suffer from epilepsy or other neurological that you may experience a severe allergic reaction with the following symptoms: tightness in the chest. you suffer from tendon problems or if you have feeling dizzy, sick or faint, or experiencing dizziness a history of tendon problems during previous when standing up, itchy skin rashes (hives), difficulty

treatment with antibiotics such as Ciprodex. you are diabetic because you may experience a risk of hypoglycaemia (low blood sugar) with doctor immediately ovou have myasthenia gravis (a type of muscle • Severe, prolonged side effects can cause

weakness), because symptoms can be disability and may be irreversible Fluoroquinolone/ quinolone antibacterial medicines, including Ciprodex, have been associated with very rare "bulge" of a large blood vessel (aortic aneurysm but serious side effects, some of them being long lasting (continuing months or years), disabling vou have experienced a previous episode of or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs. vou have been diagnosed with a leaky heart difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or vou have a family history of aortic aneurysm or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing. or other risk factors or predisposing conditions to depression, memory impairment, severe fatigue, and aortic aneurysm or dissection (e.g. connective severe sleep disorders. If you experience any of these tissue disorders such as Marfan syndrome, or side effects after taking Ciprodex, contact your doctor Ehlers-Danlos syndrome, Turner syndrome, immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment

arteritis, giant cell arteritis, Behcet's disease, high • Pain and swelling in the joints and inflammation blood pressure or atherosclerosis, rheumatoid or runture of tendons may occur rarely Your risk arthritis [a disease of the joints] or endocarditis is increased if you are elderly (above 60 years of age), have received an organ transplant, have you have heart problems. Caution should be kidney problems or if you are being treated with taken when using Ciprodex if you have or corticosteroids. Inflammation and ruptures of tendons vour family have a history of prolonged QT may occur within the first 48 hours of treatment interval (seen on ECG, electrical recording of and even up to several months after stopping the the heart), you have salt imbalance in the blood therapy. At the first sign of pain or inflammation of (especially low level of potassium or magnesium a tendon (for example in your ankle, wrist, elbow, in the blood), you have a very slow heart rhythm shoulder or knee), stop taking Ciprodex, contact (called 'bradycardia'), you have a weak heart your doctor and rest the painful area. Avoid any (heart failure), you have a history of heart attack unnecessary exercise, as this might increase the (myocardial infarction), you are female or elderly risk of a tendon rupture. Stop the treatment and or you are taking other medicines that result contact medical assistance immediately with the appearance of signs or symptoms of the following which could indicate a tendon rupture; hear or feel a you or a member of your family is known to snap or pop in a tendon area, bruising appears right

dehydrogenase (G6PD), since you may bear weight in the affected area. experience a risk of anemia with Ciprodex. For the treatment of some genital tract infections. your doctor can prescribe another antibiotic in

addition to Ciprodex. If there is no improvement You should not take fluoroquinolone/quinolone in symptoms after 3 days of treatment, please • If you begin to experience rapid attacks of shortness of breath, especially when fully lying down or if you

risk of symptoms such as pain or swelling in the **new instance of heart palpitations** (feeling of rapid bones joints or tendons while taking Ciprodex

While taking the medicine

ell your doctor immediately, if any of the fluoroquinolone. In this situation, you should inform following occurs while taking Ciprodex. Your doctor will decide whether treatment with

> Severe, sudden allergic reaction (an anaphylactic breathing or swallowing, swelling of the lips, tongue. face, throat tightness, hoarseness, rapid pulse, If this happens, stop taking Ciprodex and contact your

considering also an antibiotic from another class.

have a deficiency in glucose-6-phosphate after an injury in a tendon area, inability to move or

 If you feel sudden, severe pain in your abdomen. chest or back, which may be a sign of an aortic aneurvsm or dissection, go immediately to an emergency room. The risk may increase if you are treated with systemic corticosteroids.

tenderness of the stomach, contact your doctor notice swelling in the ankles, feet or stomach or a immediately. If you have jaundice (vellowing of

or irregular heart beat) inform the doctor immediately If you suffer from epilepsy or other neurological

conditions (such as cerebral ischemia or stroke). the skin and the eves) or dark urine. stop taking . caffeine you may experience side effects associated with the central nervous system. If seizure happens. immediately

 You may rarely experience symptoms of neuropathy Peripheral Nerve Disease) such as pain, burning. ingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens. stop taking the medicine and contact your doctor notentially irreversible condition ou may experience psychiatric reactions after that you are taking the medicine.

taking antibiotics from the fluoroquinolone group, Drug interactions with Ciprodex. In rare cases, depression or drugs and nutritional supplements. behavior, stop taking the medicine and contact your also section 2 "Do not use the medicine if"). doctor immediately

 Quinolone antibiotics may cause an increase of your blood sugar levels above normal levels nyperglycaemia), or lowering of your blood sugar levels below normal levels (hypoglycaemia), otentially leading to loss of consciousness vpoglycaemic coma) in severe cases (see section This is important for people who have diabetes. you suffer from diabetes, your blood sugar should e carefully monitored.

 Diarrhoea may develop while you are takin antibiotics, including Ciprodex, or even several weeks after you have stopped taking them. If it becomes severe or persistent or you notice that your stool contains blood or mucus, stop taking the medicine and contact your doctor immediately, as this can be life-threatening. You may have stomach cramps and a fever. Do not take medicines that stop or slow down howel movements

· If your evesight becomes impaired or if your eves seem to be otherwise affected, consult an eve specialist immediately.

Your skin becomes more sensitive to sunlight or ultraviolet (UV) light when taking Ciprodex. Avoid exposure to strong sunlight or artificial UV light such as sunbeds or sunlamps. The symptoms may include a severe sunburn, blisters or swelling of your skin. If you get any of these symptoms, contact your doctor immediately. Take care of proper protection clothes that cover your skin, hat, sunscreens etc.).

Tell the doctor or laboratory staff that you are taking Ciprodex if you have to provide a blood or urine

If you suffer from kidney problems, tell the doctor Ciprodex may increase the levels of the because your dose may need to be adjusted. • Ciprodex may cause liver damage. If you notice • pentoxifylline (for circulatory disorders) any symptoms such as loss of appetite, itching or

 Ciprodex may cause a reduction in the number or incontinence) stop taking the medicine and contact your doctor of white blood cells and your resistance to • lidocaine (for heart conditions or anaesthetic use) infection may be decreased. If you experience • sildenafil (e.g. for erectile dysfunction) an infection with symptoms such as fever and serious • agomelatine (for depression) deterioration of vour general condition, or fever Some medicines reduce the effect of Ciprodex. with local infection symptoms such as sore throat/ pharynx/mouth or urinary problems, you should see antacids the doctor immediately. A blood test will be taken to omeorazole immediately in order to prevent the development of check possible reduction of white blood cells count • mineral supplements (agranulocytosis). It is important to inform your doctor • sucralfate (for ulcer)

including Ciprodex, even after taking the first dose. Tell your doctor or pharmacist if you are • didanosine f you suffer from depression or psychosis, your taking, have recently taken or might take any • medicines or supplements containing calcium symptoms may become worse under treatment other medicines. including non-prescription magnesium, aluminum or iron

psychosis can progress to thoughts of suicide and Do not take Ciprodex together with Tizanidine (a self-harming behavior such as suicide attempts or medicine used to treat muscle spasticity in multiple completed suicide (see section 4: "Side effects"). In sclerosis), because this may cause side effects case of depression, psychosis, suicidal thoughts or such as low blood pressure and sleepiness (see Use of this medicine and food

The following medicines are known to interact

with Ciprodex. Taking Ciprodex together with these medicines can influence the therapeutic effect of those medicines and it can also increase the probability of experiencing side effects.

Tell your doctor if you are taking:

psoriasis, rheumatoid arthritis)

phenytoin (for epilepsy)

clozapine, olanzapine (an antipsychotic)

metoclopramide (for nausea and vomiting)

cvclosporin (for skin conditions, rheumatoid)

other medicines that can alter your heart rhythm:

increase your risk of central nervous system

medicines to treat diabetes (such as glibenclamide)

ropinirole (for Parkinson's disease)

arthritis and in organ transplantation)

zolpidem (for sleep disorders)

following medicines in your blood:

effects and seizures

 vitamin K antagonists (e.g. warfarin, acenocoumarol. phenprocoumon or fluindione) or other oral anti- planning to breastfeed, consult your doctor immediately to a doctor or a hospital emergency coagulants (to thin the blood) probenecid (for aout)

this medicine"

methotrexate (for certain types of cancer. It is preferable to avoid the use of Ciprodex If you forget to take the medicine theophylline (for breathing problems)

lanthanum carbonate)

hecause the active ingredient is excreted in forgotten dose as soon as you remember. Take • Unusual feelings of pain, burning, tingling, numbness breast milk and can be harmful for your child.

Pregnancy, breastfeeding and fertility

Driving and use of machinery

Ciprodex may make you feel less alert and Therefore, make sure you know how you react to forgotten dose. the medicine before driving a vehicle or operating Continue with the treatment as recommended by medicines that belong to the group of antiarrhythmics machinery. If in doubt, consult a doctor.

(e.g. quinidine, hydroquinidine, disopyramide, As for children, they should be warned to be If you stop taking the medicine amiodarone, sotalol, dofetilide, ibutilide), tricyclic careful when riding a bicycle or playing near Even if there is improvement in your health, do Other side effects antidepressants, some antimicrobials (that belong road etc. to the group of macrolides), some antipsychotics

Important information about some of the consulting the doctor. ingredients or this medicine: a Non- Steroidal Anti - Inflammatory Drug (NSAID)

Taking an NSAIDs while you take Ciprodex may

(23 mg) per caplet, that is to say essentially the antibiotic

3. How to use this medicine

Always use this medicine according to doctor's or pharmacist instructions. Check with the doctor or pharmacist

4. Side effects if you are not sure about the dosage and manner the medicine and contact your doctor immediately. • duloxetine (for depression, diabetic nerve damage of treatment. The dosage and administration will be determined by the doctor only

> The doctor will explain to you exactly how much Ciprodex you will have to take as well as how often and for how long. This will depend on the type of infection you have and how bad it is. Tell vour doctor if vou suffer from kidnev

problems because your dose may need to be The treatment usually lasts from 5 to 21 days, but may take longer for severe infections.

# • a polymeric phosphate binder (e.g. sevelamer or no not exceed the recommended dose.

Swallow the caplet with a full glass of water. regarding the use of this medicine") Caplets can be halved/crushed. Do not chew the caplets since they are coated to mask the taste. Do try to take the medicine at around the same If these preparations are essential, take time every day Ciprodex about two hours before or six hours You can take the medicine at mealtimes or

between meals. Any calcium you take as part o a meal will not seriously affect uptake. However, If you take Ciprodex during meals, do not eat or do not take Ciprodex with dairy products such drink any dairy products (such as milk or yoghurt) as milk or yoghurt or with fortified fruit juices (e.g. or drinks with added calcium when you take the calcium-fortified orange juice). Also see section tablets, as they may affect the absorption of the "Use of this medicine and food".

active substance. Also see section 3 "How to use. Drink plenty of water during treatment with the

If you have taken a higher dosage

If you are pregnant or breastfeeding, think you If you have taken an overdose or if a child has form of blisters or ulcers in the mouth, throat, nose, to thoughts of suicide, suicide attempts or syndrome associated with impaired water may be pregnant, planning to have a baby or accidentally swallowed the medicine, proceed or pharmacist for advice before taking this room and bring the package of the medicine with

If you forget to take Ciprodex and it is:

Do not take Ciprodex during breastfeeding •6 hours or more until the next dose, take the the next dose as usual.

. Less than 6 hours until the next dose, do not take the forgotten dose. Take the next dose as usual. cause some neurological adverse effects. Do not take a double dose to make up for a • Adrug reaction that causes rash, fever inflammation

not stop the treatment of this medicine without It is important that you finish the course of

his medicine contains lactose. If you have been treatment, even if you begin to feel better after told by a doctor in the past that you are intolerant to a few days. If you stop taking this medicine too certain sugars, consult a doctor before commencing soon, your infection may not be completely cured Uncommon side effects (effects which appear and the symptoms of the infection may return or in 1-10 out of 1.000 users): This medicine contains less than 1 mmol of sodium get worse. You might also develop resistance to • joint pain in adults

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 regarding headache, dizziness, sleeping problems or taste

Like any medicine, using Ciprodex may cause side effects, in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

the use of this medicine, consult your doctor disorders

he following section contains the most serious le effects that you can recognize yourself

Stop taking Ciprodex and contact your doctor immediately in order to consider another antibiotic treatment if you notice any of the following serious side effects:

Rare side effects (effects which appear in 1 out of 10,000 users): Seizure (see in section 2 "Special warning

Very rare side effects (effects which appear in this medicine") less than one out of 10 000 users):

 Severe, sudden allergic reaction with symptoms such as tightness in the chest, feeling dizzy, sick or faint, or amounts of a blood clotting factor (thrombocytes) experience dizziness when standing up (anaphylactic • allergic reaction, swelling (oedema) or rapid reaction/shock) (see in section 2 "Special warning regarding the use of this medicine")

Muscle weakness, inflammation of the tendons regarding the use of this medicine") which could lead to rupture of the tendon. • increased blood sugar (hyperalvcaemia) decreased blood sugar (hypoglycaemia) (see in particularly affecting the large tendon at the back section 2 "Special warning regarding the use of of the ankle (Achilles tendon) (see in section ? "Special warning regarding the use of this this medicine") medicine"

\*A serious life-threatening skin rash, usually in the strange dreams, depression (potentially leading determined yet) completed suicide) (see in section 2 "Special eves and other mucous membranes such as genitals which may progress to widespread blistering or peeling of the skin (Stevens-Johnson syndrome. hallucinations toxic epidermal necrolysis).

the senses, decreased skin sensitivity, tremors or Side effects with an unknown frequency (effects for which frequency has not been determined yet)

this medicine") or muscle weakness in the extremities (neuropathy) tinnitus, loss of hearing, impaired hearing. (see in section 2 "Special warning regarding the use rapid heartbeat (tachycardia) of this medicine") expansion of blood vessels (vasodilation), low

blood pressure or fainting of internal organs. hematologic abnormalities and systemic illness [DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms), AGEP (Acute Generalised Exanthematous Pustulosis)].

white blood cell)

Common side effects (effects which appear in -10 out of 100 users): nausea, diarrhea

· joint pain and joint inflammation in children

 fungal superinfections · a high concentration of eosinophils, (a type of

decreased appetite

as stomach upset (indigestion/heartburn), or wind increased amounts of certain substances in the which may also be fatal

vomiting abdominal pain digestive problems such

increase in blood alkaline phosphatase (a certain.

Rare side effects (effects which appear in 1-10

muscle pain inflammation of the joints increased

inflammation of the bowel (colitis) linked to

warning regarding the use of this medicine")

Very rare side effects (effects which appear in

this medicine"); a drop in the number of red and

white blood cells and platelets (pancytopenia).

which may be fatal: and bone marrow depression

fluid retention or excessive sweating

less than one out of 10,000 users):

increased levels of the enzyme amylase

tract inflammation.

blood (transaminases and/or bilirubin)

rash itching or hives

poor kidney function

(asthenia) or fever

out of 10,000 users):

substance in the blood)

muscle tone and cramping

 allergic reaction called serum sickness-like section 2. reaction (see in section 2: "Special warning If you experience a side effect or if one of the regarding the use of this medicine"

pains in your muscles and bones, feeling unwell • mental disturbances (psychotic potentially leading to thoughts of suicide, suicide with the doctor. attempts or completed suicide) (see in section 2: "Special warning regarding the use of this medicine")

 migraine, disturbed coordination, unsteady walk (intracranial pressure and pseudotumor cerebri)

visual colour distortions

antibiotic use (can be fatal in very rare cases) (see in section 2 "Special warning regarding the use of

 pancreatitis changes to the blood count (leukopenia, leukocytosis,

section 2.

existing risk factors

death of liver cells (liver necrosis) very rarely neutropenia anemia) increased or decreased leading to life-threatening liver failure (see in section 2: "Special warning regarding the use of this medicine") swelling of the skin and mucous membranes small, pin-point bleeding under the skin (angio-oedema) (see in section 2 "Special warning

(petechiae); various skin eruptions or rashes • worsening of the symptoms of myasthenia gravis • Storage conditions: store at a temperature (see in section 2: "Special warning regarding the use of this medicine")

confusion, disorientation, anxiety reactions.

excretion and low levels of sodium (SIADH)

warning regarding the use of this medicine") or \*feeling highly excited (mania) or feeling great optimism and overactivity (hypomania) · pins and needles, unusual sensitivity to stimuli of · abnormal fast heart 'rhythm, life-threatening

on ECG, electrical activity of the heart) evesight problems including double vision (see in section 2 "Special warning regarding the use of influence on blood clotting (in patients treated with the package

Vitamin K antagonists) loss of consciousness due to severe decrease in both sides

Very rare cases of long lasting (up to months or marketed. • shortness of breath, including asthmatic symptoms years) or permanent adverse drug reactions, such Revised in September 2021 according to MOH liver disorders, iaundice (cholestatic icterus) or as tendon inflammations, tendon rupture, joint pain, quidelines, pain in the limbs, difficulty in walking, abnormal • sensitivity to light (see in section 2 "Special sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy) • kidney failure, blood or crystals in the urine, urinary depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, Ciprodex PIL PB1121-04 vision, and taste and smell have been associated

· a special type of reduced red blood cell count Cases have been reported of enlargement and 1 Dexcel St., Or Akiva 3060000, Israel (haemolytic anaemia); a dangerous drop in a weakness of the aortic wall or a tear in the aortic type of white blood cells (agranulocytosis) (see in wall (aneurysm and dissection), which may tear section 2: "Special warning regarding the use of and become lethal, and cases of heart valve leak

in patients taking fluoroguinolones. Also see

side effects worsens or if you suffer from any reactions side effect not listed in this leaflet, consult

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can (gait disturbance), disorder of sense of smell be found on the homepage of the Ministry of

(Olfactory disorders), pressure on the brain Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: https://sideeffects.health.gov.i

## •inflammation of the wall of the blood vessels 5. How to store the medicine · Avoid poisoning! This medicine, and all other

medicines, 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

(תאביר תפונה) stated on the package. The expiry date refers to the last day of that month.

· Do not throw away any medicines via wastewater

Side effects with an unknown frequency or household waste. Ask the pharmacist how to (effects for which frequency has not been throw away medicines you no longer use. These measures will help protect the environment.

In addition to the active ingredient, this

medicine also contains: Lactose monohydrate, sodium starch glycolate. irregular heart rhythm, alteration of the heart povidone, hypromellose, titanium dioxide.

rhythm (called 'prolongation of QT interval'. seen sodium stearyl fumarate, macrogol 400. What the medicine looks like and contents of

White to off - white biconvex caplet, scored on

blood sugar levels (hypoglycaemic coma). See Approved package sizes include 2, 5, 7, 10, 14. 20 caplets. Not all package sizes may be

> Drug registration number at the national medicines registry of the Ministry of Health:

with administration of quinolone and fluoroquinolone

Manufacturer and registration holder: antibiotics, in some cases irrespective of pre-Dexcel® Ltd