PATIENT INFORMATION LEAFLET

DYNAFLOC 500

SCHEDULING STATUS

S4

DYNAFLOC 500 tablets

Ciprofloxacin

DYNAFLOC 500 is sugar free

Read all of this leaflet carefully before you start taking DYNAFLOC 500

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DYNAFLOC 500 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DYNAFLOC 500 is and what it is used for
2. What you need to know before you take DYNAFLOC 500
3. How to take DYNAFLOC 500
4. Possible side effects
5. How to store DYNAFLOC 500
6. Contents of the pack and other information

1. What DYNAFLOC 500 is and what it is used for

DYNAFLOC 500 belongs to a group of antibiotics called fluoroquinolones. DYNAFLOC 500 works by killing bacteria that cause infections. It only works with specific strains of bacteria.

DYNAFLOC 500 is used in adults to treat severe and/or complicated bacterial infection of the lungs, bladder, gut (diarrhoea), bone, or skin and soft tissues where other antimicrobials used for similar

infections were considered not to be an appropriate treatment option, have failed, cannot be used or are not tolerated. It is also used to prevent you getting an infection caused by a bacterium called *Neisseria meningitidis*.

2. What you need to know before you take DYNAFLOC 500

Do not take DYNAFLOC 500:

- if you are hypersensitive (allergic) to ciprofloxacin and other quinolones, or to any of the ingredients of DYNAFLOC 500 (see section 6)
- if you are on treatment for high blood pressure with medicines called ACE inhibitors/angiotensin receptor blockers. Ask your doctor if you are unsure
- if you also use medicine containing fluoroquinolones and have moderate to severe kidney impairment
- if you were born with or have any condition with abnormal heart rhythm whether related to QT time prolongation or not (seen on ECG, electrical recording of the heart)
- if you are taking other medicines that result in abnormal heart rate and/or rhythm tracing (ECG) e.g. prolongation of the “QT time”
- if you or your child are younger than 18 years
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding)
- if you have myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases, paralysis)
- if you have previously experienced side effects with the use of quinolone/fluoroquinolone antibiotics relating to your joints, muscles, ligaments, nerves, central nervous system (brain), epilepsy or mental health (psychiatric disorder)
- if you have an enlargement or “bulge” of a large blood vessel (aortic aneurysm) or a previous episode of aortic dissection (a tear in the aortic wall) or a family history of aortic aneurysm/dissection or other risk factors or existing predisposing conditions).

Warnings and precautions

Take special care with DYNAFLOC 500:

Tell your doctor:

- if have ever had kidney problems as your doctor may need to adjust the dose
- if you have heart problems. Caution should be taken when using DYNAFLOC 500, if you are born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm rate (called 'bradycardia'), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see Do not take DYNAFLOC 500 and Other medicines and DYNAFLOC 500)
- if you have a family history of aortic aneurysm or aortic dissection or other risk factors or existing predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure or known atherosclerosis)
- if you suffer from depression or other mental health problems
- if you suffer from epilepsy or other neurological conditions, such as fits
- if you have a history of tendon problems during previous treatment with antibiotics such as DYNAFLOC 500 (see Do not take DYNAFLOC 500)
- if you have myasthenia gravis (a type of muscle weakness) (see Do not take DYNAFLOC 500)
- if you have diabetes
- if you are currently taking other medicines that can reduce your blood potassium levels
- if you have a damaged mitral and/or aortic heart valve which cannot close properly
- if you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anaemia with DYNAFLOC 500.

If any of the following occurs while taking this medicine, tell your doctor immediately, he/she will decide whether treatment with DYNAFLOC 500 needs to be stopped:

- Severe, sudden allergic reaction (an anaphylactic reaction/shock, angioedema). Even with the first dose, there is a risk that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, sick or faint, or experiencing dizziness when standing up. If this happens, stop taking DYNAFLOC 500 and contact your doctor immediately.
- if you notice any severe skin reactions, as you could have developed a severe disorder, such as Stevens-Johnson syndrome (a skin condition that causes painful blisters and sores of the skin and mucous membranes, especially in the mouth), toxic epidermal necrolysis (a serious condition with blistering of the skin) or drug reaction with eosinophilia and systemic symptoms (a medicine reaction that causes rash, fever, facial swelling, inflammation of internal organs, hematologic abnormalities and systemic illness), any of which could be life-threatening or fatal.
- If you suffer from diarrhoea while taking DYNAFLOC 500, stop taking it and contact your doctor immediately as this may become life-threatening.
- DYNAFLOC 500 may cause liver damage. If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching, or tenderness of the stomach, stop taking this medicine and contact your doctor immediately.
- Pain and swelling in the joints and tendons (inflammation of your ligaments) may occur, particularly if you are elderly and are also being treated with corticosteroids. Inflammation and tearing of tendons may occur even within the first 48 hours of treatment or up to several months after stopping therapy.

  At the first sign of any pain or inflammation stop taking this medicine and rest the painful area. Avoid any unnecessary exercise, as this might increase the risk of your tendon tearing. The recovery process for your tendons, muscles and joints may take weeks or months and full recovery to what it was before treatment with this medicine may not occur (see Do not take DYNAFLOC 500).

- If you experience several epileptic fits after one another without recovery of consciousness between them (see Do not take DYNAFLOC 500).
- You may experience mental health problems (psychiatric reactions) the first time you take DYNAFLOC 500. If you suffer from depression or psychosis, your symptoms may become worse under treatment with this medicine. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If you experience feelings of hurting yourself, stop taking DYNAFLOC 500 and contact your doctor immediately. (see Do not take DYNAFLOC 500).
- You may experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness in your limbs. If this happens, stop taking this medicine and contact your doctor immediately.

  The recovery process for your nerve condition may take weeks or months and full recovery (to what it was before your treatment with DYNAFLOC 500) may not occur (see Do not take DYNAFLOC 500).
- Your skin may become more sensitive to sunlight or ultraviolet (UV) light when taking this medicine. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.
- DYNAFLOC 500 may interfere with the results of blood or urine laboratory tests, including the culture test for tuberculosis – tell the doctor or laboratory staff that you are taking DYNAFLOC 500.
- Quinolone antibiotics may cause an increase of your blood sugar levels above normal levels (hyperglycaemia), or lowering of your blood sugar levels below normal levels, potentially leading to loss of consciousness (hypoglycaemic coma) in severe cases (see section 4). This is important for people who have diabetes. If you suffer from diabetes, your blood sugar should be carefully monitored.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

For the treatment of some genital tract infections, your doctor can prescribe another antibiotic in addition to DYNAFLOC 500. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

Other medicines and DYNAFLOC 500

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines.)

- do not take DYNAFLOC 500 together with tizanidine, because this may cause side effects such as low blood pressure and sleepiness (see Do not take DYNAFLOC 500)
- Medicines that can affect your heart rhythm: medicines that belong to the group of Class IA and III anti-dysrhythmics, tricyclic antidepressants, some antibiotics (that belong to the group of macrolides), some antipsychotics (used for schizophrenia)
- Medicines which reduce the effect of DYNAFLOC 500. If these medicines are essential, take DYNAFLOC 500 about two hours before or no sooner than four hours after them. They include:
    - sucralfate (used to treat heartburn, indigestion or ulcers in the stomach or intestines)
    - antacids (used to treat indigestion)
    - highly buffered medicines such as didanosine (used to treat HIV)
    - a polymeric phosphate binder such as sevelamer, lanthanum carbonate (to lower the level of phosphates in patients with kidney problems)
    - medicines or dietary supplements containing calcium, magnesium, aluminium or iron.
- Probenecid (a medicine used to prevent gout) and DYNAFLOC 500 increase the blood levels of DYNAFLOC 500
- Metoclopramide (for nausea and vomiting)
- Omeprazole (for heartburn, indigestion or ulcers in the stomach or intestines)
- Concomitant use of DYNAFLOC 500 with theophylline (a medicine used to treat asthma), may increase the theophylline levels in your blood. Your doctor may need to adjust your dose
- Pentoxifylline (for circulation disorders)

- Phenytoin (for epilepsy)
- Methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- Concomitant use of nonsteroidal anti-inflammatory medicine fenbufen with quinolones like DYNAFLOC 500 may lead to seizures. Your doctor will perform regular blood tests if you are considered to be at risk
- Ciclosporin (for skin conditions, rheumatoid arthritis and in organ transplants)
- Simultaneous use of DYNAFLOC 500 and warfarin (a medicine used to prevent blood clots), may intensify the action of warfarin
- Using DYNAFLOC 500 with glibenclamide (a medicine used to treat high blood sugar), can increase the effect of glibenclamide
- Duloxetine (for depression, diabetic nerve damage or incontinence)
- Ropinirole (for Parkinson's disease)
- Lidocaine (lignocaine) (for heart conditions or anaesthetic use)
- Clozapine (antipsychotic – used for schizophrenia)
- Sildenafil (e.g. for impotence or high blood pressure)
- If you are on treatment with ACE inhibitors/angiotensin receptor blockers used to control your blood pressure. Ask your doctor if you are not sure
- Agomelatine (for depression)
- Zolpidem (for sleep disorders).

DYNAFLOC 500 with food and drink

DYNAFLOC 500 may be taken with or without meals.

Do not eat or drink any dairy products (such as milk, yoghurt or cheese) or drinks with added calcium when you take the tablets, as they may affect the absorption of the active substance and this medicine may not work properly.

Pregnancy, breastfeeding and fertility

You should not take DYNAFLOC 500 during pregnancy or when breastfeeding your baby.

Safety during pregnancy and breastfeeding has not been established.

DYNAFLOC 500 is excreted in your breast milk and may harm your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking DYNAFLOC 500.

Driving and using machines

This medicine may affect your ability to drive and operate machinery. Do not drive, operate machinery, or do anything else that could be dangerous until you know how you react to DYNAFLOC 500.

It is not always possible to predict to what extent DYNAFLOC 500 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DYNAFLOC 500 affects them.

3. How to take DYNAFLOC 500

Do not share medicines prescribed for you with any other person. Always use DYNAFLOC 500 exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Your doctor will decide on your dose and adjust your dose where necessary, depending on your condition and whether you are an elderly patient. This will depend on the type and severity of infection you have.

Adults:

DYNAFOC 500 should be swallowed whole with plenty of liquid.

The dosage range is 250 - 750 mg twice daily

The treatment usually lasts from 5 - 21 days, but may take longer for severe infections.

For the treatment of invasive infections of *Neisseria meningitides* (a Gram-negative bacterium that can

cause meningitis and other forms of meningococcal disease such as meningococcemia, a life-threatening sepsis), take one single dose of 500 mg.
Do not change the dose prescribed by your doctor.

Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted.

Elderly
Elderly patients should receive a dose as low as possible depending on the severity of their illness and how well their kidneys are working.

You can take the tablets at meal times or between meals. Any calcium you take as part of a meal will not seriously affect uptake. However, do not take DYNAFLOC 500 with dairy products such as milk or yoghurt or with fortified fruit juices (e.g. calcium fortified orange juice).
Remember to drink plenty of fluids while you are taking this medicine.

Your doctor will tell you how long your treatment with DYNAFLOC 500 will last. Do not stop treatment early because your infection may not be cleared.
If you have the impression that the effect of DYNAFLOC 500 is too strong or too weak, tell your doctor or pharmacist.

If you take more DYNAFLOC 500 than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take DYNAFLOC 500
It is important to take your medicine every day. However, if you forget to take one or more doses, take

another as soon as you remember and then go on as prescribed on a normal daily dose. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking DYNAFLOC 500

It is important that you finish the course of treatment even if you begin to feel better after a few days. If you stop taking this medicine too soon, your infection may not be completely cured and the symptoms of the infection may return or get worse. You might also develop resistance to the antibiotic.

4. Possible side effects

DYNAFLOC 500 can have side effects.

Not all side effects reported for DYNAFLOC 500 are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using DYNAFLOC 500, please consult your healthcare provider for advice.

If any of the following happens, stop using DYNAFLOC 500 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DYNAFLOC 500. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- sudden severe pain in your chest, abdomen (tummy) or back, fast or pounding heartbeats (QT prolongation), chest pain

- serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (very rare side effects, potentially life-threatening)
- sudden pain, snapping or popping sound, bruising, swelling, tenderness, stiffness, or loss of movement in any of your muscles, ligaments, tendons, or joints
- worsening of myasthenia gravis (abnormal muscle weakness)
- increase in liver enzymes and jaundice (characterised by yellowing of skin and eyes), inflammation of the liver, and very seldom, liver failure
- suicidal thoughts, self-endangering behaviour, seeing and hearing things that are not really there, feeling sad for prolonged periods of time, feeling confused, nervous, agitated and anxious, disorientation, confusion, hallucinations
- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis)
- seizure (convulsions), disturbed coordination
- epilepticus (prolonged or repeated fits or seizures without any recovery between attacks)
- inflammation of blood vessels, known as vasculitis (signs could be red spots on your skin, usually on your lower legs or effects like joint pain).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea, diarrhoea.

Less frequent side effects:

- superinfections, fungal infections

- blood disorders identified through blood tests, leukopenia, anaemia, neutropenia, leucocytosis (changes in blood count), thrombocytopenia or thrombocytaemia (increased or decreased amounts of blood platelets), haemolytic anaemia (a special type of anaemia due to red blood cell destruction), agranulocytosis (a drop in a type of white blood cells), or pancytopenia (a dangerous drop in the number of red and white blood cells and platelets) which may be life-threatening; or bone marrow depression, which may also be life-threatening
- low blood sugar (hypoglycaemia) in diabetic patients, high blood sugar (hyperglycaemia), diabetic coma, lack of appetite (anorexia)
- feeling nervous, agitated and anxious, nightmares, abnormal dreams
- headache, dizziness, sleep problems (insomnia), impaired taste and smell, trembling, paraesthesia ('pins and needles'), dysesthesia (disturbed sensation) or hypoesthesia (reduced sensation), vertigo, migraine, disturbed coordination, hyperesthesia (increased sensitivity to stimuli), or intracranial hypertension including pseudotumour cerebri (pressure on the brain)
- visual disturbances (eyesight problems), visual colour distortions
- temporary hearing impairment, ringing in your ears (tinnitus), loss of hearing
- tachycardia (rapid heartbeat)
- hot flushes, vasodilatation (expansion of blood vessels), hypotension (low blood pressure)
- dyspnoea (shortness of breath) including asthmatic condition
- vomiting, dyspepsia (indigestion), stomach pain, excessive gas in the stomach (flatulence), pancreatitis (inflammation of the pancreas)
- hepatic impairment (liver disorders), non-infective hepatitis
- photosensitivity reactions (sensitivity to light), or blistering (blistering of the skin), petechiae (small, pin-point bleeding under the skin), erythema multiforme, erythema nodosum (various skin eruptions, blisters, peeling or rashes, itching)

- joint pain, joint swelling, feeling weak, muscle pains, tenosynovitis (inflamed tendons), arthritis (inflammation of the joints), or increased muscle tone and cramping, muscular weakness, extremity pain, back pain
- kidney problems (interstitial nephritis, impairment in kidney function, cloudy urine, blood in the urine), renal failure (kidney failure), haematuria (blood in the urine), crystalluria (crystals in the urine) or tubulointerstitial nephritis (a type of urinary tract inflammation)
- tiredness, sweating, unspecific pain, feeling unwell, fluid retention
- abnormal prothrombin (a clotting factor) level or increased amylase (increased levels of the enzyme amylase), increased alkaline phosphatase (a certain substance in the blood).

The following side effects have been reported but the frequency for them to occur is not known:

- syndrome associated with impaired water excretion and low levels of sodium (SIADH) (your body retains water instead of excreting it normally in urine, which upsets the body's balance of minerals called electrolytes, especially sodium)
- mental and physical hyperactivity (mania), over-active and excited behaviour (hypomania)
- weakness, numbness and pain in hands and feet
- a medicine reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS: drug reaction with eosinophilia and systemic symptoms, AGEP: acute generalised exanthematous pustulosis)
- influence on blood clotting (in patients treated with anticoagulants such as warfarin).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of DYNAFLOC. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store DYNAFLOC 500

Store all medicines out of the reach of children.

Store at or below 25 ºC, in a cool, dry place. Protect from light. Keep the blisters in the carton until required for use.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DYNAFLOC 500 contains:

The active substance is ciprofloxacin.

DYNAFLOC 500: Each tablet contains ciprofloxacin hydrochloride monohydrate, equivalent to ciprofloxacin 500 mg.

The other ingredients are:

Tablet cores:

The other ingredients are: anhydrous colloidal silicon, crospovidone, magnesium stearate, microcrystalline cellulose.

Coating:

Opadry Y-1-7000 (hypromellose, macrogol 400, titanium dioxide)

What DYNAFLOC 500 looks like and contents of the pack

DYNAFLOC 500: White or yellowish, 18 mm x 8 mm oblong, biconvex, film coated tablets, scored on one side.

PVC/Aluminium Blister packs of 10 tablets.

Holder of Certificate of Registration

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