

## PATIENT INFORMATION LEAFLET

### DYNAFLOC 500

#### SCHEDULING STATUS:

S4

#### PROPRIETARY NAME AND DOSAGE FORM:

**DYNAFLOC 500** (tablets)

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

- Keep this leaflet. You may need to read it again.
- If have further questions, please ask your doctor or your pharmacist.
- **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.

#### 1. WHAT **DYNAFLOC 500** CONTAINS

The active substance is ciprofloxacin.

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

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

**DYNAFOC 500** is sugar free.

#### 2. WHAT **DYNAFLOC 500** IS USED FOR

**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*.

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#### 3. BEFORE YOU TAKE DYNAFLOC 500

##### Do not take DYNAFLOC 500

**DYNAFLOC 500** must not be used in children under 18 years and in growing adolescents, except if your doctor tells you to do so.

- if you are hypersensitive (allergic) to ciprofloxacin and other quinolones, or any of the other ingredients in the tablet (see **WHAT DYNAFLOC 500 CONTAINS**).
- if you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).
- if you are taking any medicine that inhibits the constriction and relaxation of the muscles of the intestines (peristalsis).
- 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 an abnormal heart rate and/or rhythm tracing (ECG) e.g. (prolongation of the “QT time”).
- 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 myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases, paralysis).
- 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).
- if you also use medicine containing fluoroquinolones and have moderate to severe kidney impairment.
- 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 or your child are younger than 18 years.**

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#### Take special care with DYNAFLOC 500

- if you are currently taking other medicines that can reduce your blood potassium levels.
- 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 (see **Do not take DYNAFLOC 500**).
- **DYNAFLOC 500** may interfere with the interpretation of diagnostic culture tests for tuberculosis.
- if you experience several epileptic fits after one another without recovery of consciousness between them (see **Do not take DYNAFLOC 500**)
- if you experience feelings of hurting yourself (see **Do not take DYNAFLOC 500**).

#### Taking DYNAFLOC 500 with food and drink

**DYNAFLOC 500** may be taken with or without meals.

#### Pregnancy and breastfeeding:

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

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **DYNAFLOC 500**.

Safety during pregnancy and breastfeeding has not been established.

#### Driving and using machinery:

Do not drive, operate machinery, or do anything else that could be dangerous until you know how you react on **DYNAFLOC 500**.

#### Taking other medicines with DYNAFLOC 500:

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **DYNAFLOC 500** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare provider, for advice.

- 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.
- **DYNAFLOC 500** tablets should be taken 1 – 2 hours before, or at least 4 hours after taking medicine containing iron and medicines that reduce stomach acid (containing magnesium, aluminium, calcium or sucralfate), as these medicines may interfere with the absorption of **DYNAFLOC 500**.
- 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.
- 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.
- Probenecid (a medicine used to prevent gout) and **DYNAFLOC 500** increase the blood levels of **DYNAFLOC 500**.
- 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.

#### 4. HOW TO TAKE DYNAFLOC 500

Always take **DYNAFLOC 500** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **DYNAFLOC 500**

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is too strong or too weak, tell your doctor or pharmacist. Do not share medicines prescribed for you with any other person.

**DYNAFLOC 500** tablets should be swallowed whole with plenty of liquid.

Your doctor will decide on your dose and adjust your dose where necessary, depending on your condition and whether you are an elderly patient.

**DYNAFLOC 500** is not suitable for use in children.

#### **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 a dose of 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.

## **5. POSSIBLE SIDE EFFECTS**

**DYNAFLOC 500** can have side effects. If any of the following happens, stop taking **DYNAFLOC 500** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the face, lips, tongue, throat and airways (breathing tubes), difficult breathing, blueness of the skin, low blood pressure, heart failure and can result in death.

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:

- fast heartbeat

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- Stevens Johnson Syndrome (a severe skin condition including a purplish rash and blisters)
- Lyell Syndrome (a serious skin condition characterised by destruction and detachment of the skin)
- dizziness and visual disturbances
- worsening of myasthenia gravis (abnormal muscle weakness)
- tendon rupture (predominantly the Achilles tendon), muscle weakness and inflammation of tendons (tendinitis), increased muscle tone and cramping
- fainting
- 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
- nightmares
- low blood sugar in diabetic patients, high blood sugar, diabetic coma
- convulsions (fits)
- kidney problems (interstitial nephritis, impairment in kidney function, cloudy urine, blood in the urine).

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
- diarrhea.

Less frequent side effects:

- recurring infections, fever

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- hot flushes, sweating
- tiredness, sensitivity to light
- joint pain, joint swelling, feeling weak, muscle pains, tenosynovitis (inflamed tendons)
- arthralgia (joint pain), myalgia (muscle pain), inflammation and swelling of the joints (arthritis)
- nausea, diarrhoea, vomiting, dyspepsia, stomach pain, excessive gas in the stomach (flatulence), a lack of appetite (anorexia)
- temporary hearing impairment, ringing in your ears (tinnitus)
- headache, trembling, struggling to sleep (insomnia), migraine
- impaired taste and smell
- disordered sensibility to pain, weakness, numbness and pain in hands and feet, unsteady walking
- blood disorders identified through blood tests
- rash, itching, vasculitis and other skin disorders
- sudden severe pain in your chest, abdomen (tummy) or back.

Not all side effects reported for **DYNAFLOC 500** are included in this leaflet.

Should your general health worsen while taking **DYNAFLOC 500**, please consult your healthcare provider for advice.

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

#### 6. STORING AND DISPOSING OF DYNAFLOC 500

- Store at or below 25 °C, in a cool dry place.
- Protect from light.
- Keep the blisters in the carton until required for use.
- Do not store your medicine in the bathroom.
- Do not take **DYNAFLOC 500** after the expiry date stated on the carton.
- Return any expired or unused medicine to your pharmacist for safe disposal.

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- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- **KEEP OUT OF REACH OF CHILDREN.**