Clean Proposed Patient Information Leaflet for Medicines for Human Use:

FLOQIN IV 2 mg/mL

SCHEDULING STATUS:

S4

FLOQIN IV 2 mg/mL Solution for Infusion

Ciprofloxacin

Read all of this leaflet carefully before you start taking FLOQIN IV 2 mg/mL

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

What is in this leaflet

1. What FLOQIN IV 2 mg/mL is and what it is used for

2. What you need to know before you take FLOQIN IV 2 mg/mL

3. How to take FLOQIN IV 2 mg/mL

4. Possible side effects

5. How to store FLOQIN IV 2 mg/mL

6. Contents of the pack and other information

1. What FLOQIN IV 2 mg/mL is and what it is used for

FLOQIN IV 2 mg/mL contains the active substance ciprofloxacin. FLOQIN IV 2 mg/mL is an antibiotic belonging to the fluoroquinolone family.

FLOQIN IV 2 mg/mL 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.

2. What you need to know before you take FLOQIN IV 2 mg/mL

Do not take FLOQIN IV 2 mg/mL

- if you are allergic to ciprofloxacin, ~~to~~ any other quinolone medicines, or to any of the other ingredients of this medicine (listed in section 6)**,**
- **if you or your child are younger than 18 years~~,~~**
- you are using tizanidine, a medicine used to treat muscle spasms,
- 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 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 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 are on treatment for high blood pressure with medicines called ACE inhibitors/angiotensin receptor blockers (ARBs). Ask your doctor if you are unsure,

- if you have mitral valve and or/aortic valve regurgitation (a heart condition where the mitral and/or aortic valve does not close properly),
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with FLOQIN IV 2 mg/mL

Tell your doctor before taking FLOQIN IV 2 mg/mL

- if you have ever had kidney problems because your treatment may need to be adjusted,
- if you suffer from epilepsy or other neurological conditions,
- if you are diabetic because you may experience a risk of hypoglycaemia (low blood sugar) with FLOQIN IV 2 mg/mL,
- if you have heart problems. Caution should be taken when using FLOQIN IV 2 mg/mL, if you were 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 (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 USING OTHER MEDICINES WITH FLOQIN IV 2 mg/mL),
- 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 (a decrease in red blood cells which can lead to you feeling extremely tired) with FLOQIN IV 2 mg/mL,
- if you are taking a medicine called methotrexate, used to treat certain types of cancer, rheumatoid arthritis,

- 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 FLOQIN IV 2 mg/mL),
- if you are currently taking medicines for high blood pressure called ACE inhibitors/angiotensin receptor blockers (ARBs) and are elderly or already have impaired kidney function, FLOQIN IV 2 mg/mL can cause acute kidney injury (see Do not take FLOQIN IV 2 mg/mL),
- if you have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated (see Do not take FLOQIN IV 2 mg/mL),
- if you are going for a test for mycobacteria such as a tuberculosis (TB) test, as FLOQIN IV 2 mg/mL may interfere with the interpretation of diagnostic culture tests for tuberculosis.

Tell your doctor immediately if during treatment you suffer from:

- Severe, sudden allergic reaction (an anaphylactic reaction/shock, angioedema). Even with the first dose, there is a chance that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing. If this happens, tell your doctor immediately since the administration of FLOQIN IV 2 mg/mL will have to be stopped.
- Pain and swelling in the joints, and tendinitis may occur, particularly if you are elderly and are also being treated with corticosteroids. If you develop pain or swelling in your tendons, tell your doctor immediately since the administration

of FLOQIN IV 2 mg/mL will have to be stopped. Avoid any unnecessary exercise as this may increase the risk of a tendon rupture (see Do not take FLOQIN IV 2 mg/mL).

- You may experience psychiatric reactions after first administration of FLOQIN IV 2 mg/mL. If you suffer from depression or psychosis, your symptoms may become worse under treatment with FLOQIN IV 2 mg/mL. Depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, stop taking FLOQIN IV 2 mg/mL and contact your doctor immediately.
- Diarrhoea may develop while you are on antibiotics, including, FLOQIN IV 2 mg/mL or even several weeks after you have stopped using them. If it becomes severe or persistent or you notice that your stool contains blood or mucus tell your doctor immediately. FLOQIN IV 2 mg/mL treatment will have to be stopped immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements.
- Your skin becomes more sensitive to sunlight or ultraviolet (UV) light under treatment with FLOQIN IV 2 mg/mL. Avoid exposure to strong sunlight or artificial UV light such as sunbeds.
- FLOQIN IV 2 mg/mL 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, FLOQIN IV 2 mg/mL must be stopped immediately.
- If you suffer from kidney problems, tell the doctor because your dose may need to be adjusted.
- If you experience pain, burning, tingling, numbness and/ or muscle weakness, inform your doctor immediately since the administration of FLOQIN IV 2 mg/mL will have to be stopped.

- If your ability to see is impaired or your eyes seem to be otherwise affected, consult an eye specialist immediately.

Children and adolescents

Do not use FLOQIN IV 2 mg/mL is you are under 18 years old (see Do Not Take FLOQIN IV 2 mg/mL).

Other medicines and FLOQIN IV 2 mg/mL

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines are known to interact with FLOQIN IV 2 mg/mL in your body. Using FLOQIN IV 2 mg/mL together with these medicines can influence the therapeutic effect of these medicines. It can also increase the probability of experiencing side effects.

Tell your doctor if you are taking:

- Vitamin K antagonists (e.g. warfarin or fluindione) or other oral anti-coagulants (to thin the blood),
- probenecid (for gout),
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis),
- olanzapine or clozapine (antipsychotics),
- ropinirole (for Parkinson’s disease),
- theophylline (for breathing problems),
- phenytoin (for epilepsy),

- ciclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation),
- zolpidem (for sleep disorders),
- omeprazole (for heartburn and ulcers),
- other medicines that can alter your heart rhythm: medicines that belong to the group of antiarrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.
- ACE inhibitors/angiotensin receptor blockers (ARBs). Ask your doctor if you are not sure (see Do not take FLOQIN IV 2 mg/mL)

FLOQIN IV 2 mg/mL may increase the levels of the following medicines in your blood:

- pentoxifylline (for circulatory disorders),
- caffeine,
- duloxetine (for depression),
- lidocaine (for heart conditions or anaesthetic use),
- sildenafil (for erectile dysfunction)
- agomelatine (for depression).

If you are taking a medicine called tizanidine (used to treat muscle spasms), you should not receive FLOQIN IV 2 mg/mL.

FLOQIN IV 2 mg/mL with food and drink:

Your doctor or a nurse will administer FLOQIN IV 2 mg/mL to you.

Pregnancy and Breastfeeding

You should not use FLOQIN IV 2 mg/mL during pregnancy or when breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before receiving FLOQIN IV 2 mg/mL.

Driving and using machines

FLOQIN IV 2 mg/mL may affect your ability to drive or to use machinery. FLOQIN IV 2 mg/mL may make you feel less alert and may affect your reaction time.

It is not always possible to predict to what extent FLOQIN IV 2 mg/mL 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 FLOQIN IV 2 mg/mL affects them.

I**mportant information about some of the ingredients of FLOQIN IV 2 mg/mL**

Sodium

FLOQIN IV 2 mg/mL contains sodium chloride per 100 mL of solution, therefore this medicine may not be suitable for you if you are on a low sodium diet. Check with your doctor if you are unsure about this.

3. How to take FLOQIN IV 2 mg/mL

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself FLOQIN IV 2 mg/mL. It will be given to you by a person who is qualified to do so.

Treatment usually lasts for 7 days but may be longer for severe infections.

Your doctor will give you each dose by slow infusion through a vein into your bloodstream.

In adult patients, infusion time is 60 minutes. Administering the infusion slowly helps prevent immediate side effects occurring.

If you have the impression that the effect of FLOQIN IV 2 mg/mL is too strong or too weak, you should talk to your doctor or pharmacist.

If you receive more FLOQIN IV 2 mg/mL than you should:

Since a healthcare professional will administer FLOQIN IV 2 mg/mL, he/she will control the dosage. However, in the event of over-dosage, your doctor will manage the over-dosage.

If you miss a dose of FLOQIN IV 2 mg/mL

As you will be given FLOQIN IV 2 mg/mL under close supervision, it is unlikely that you will miss a dose. If you feel that you have missed a dose of treatment, tell your doctor or nurse immediately.

If you have any further questions on the use of FLOQIN IV 2 mg/mL, ask your doctor or pharmacist.

4. Possible side effects

FLOQIN IV 2 mg/mL can have side effects.

Not all side effects reported for FLOQIN IV 2 mg/mL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving FLOQIN IV 2 mg/mL, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking FLOQIN IV 2 mg/mL and tell your doctor immediately or go to the casualty department at your nearest hospital

- severe sudden allergic reactions (e.g.: 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.

If any of the following happens tell your doctor or healthcare professional immediately to stop administering FLOQIN IV 2 mg /mL

- skin reactions such as red sore skin and flaking (dermatitis), rash, itching, or swelling, of the tongue, throat, the face and neck. These may be signs of a serious allergic reaction,
- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which in some circumstances may develop into complications that are life-threatening,
- recurrent nausea or vomiting, abdominal pain or rapid breathing,
- abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called ‘prolongation of QT interval’, seen on ECG, electrical activity of the heart),
- kidney failure, which may cause changes in urination; swelling of the feet, ankles, hands or face; shortness of breath, or feeling weak,
- skin rash with or without itching, a fever and swelling of the lymph glands. The liver, kidneys or lungs could also be affected. This is a reaction which may develop weeks or months after your last dose of FLOQIN IV 2 mg/mL,
- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal),
- changes to the blood count (leukopenia, leukocytosis, neutropenia, anaemia), a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal, bone-marrow depression (you may feel tired, experience shortness of breath, easy bruising, or bleeding) which may also be fatal.

These are very serious side effects. If you have them, you may have had a serious reaction to FLOQIN IV 2 mg/mL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- sudden severe pain in your chest, abdomen (tummy) or back,
- local reaction at the injection site, rash,
- muscle pain, inflammation of the joints, increased muscle tone, cramping, tendon rupture – especially of the large tendon at the back of the ankle (Achilles tendon),
- feelings of great excitement or euphoria (mania), or feeling of great optimism and overactivity (hypomania),
- headache, dizziness, sleeping problems, taste disorders, pins and needles, unusual sensitivity to stimuli of the senses, seizures, giddiness.

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,
- running stomach (diarrhoea),
- throwing up (vomiting),
- increase in transaminases (liver enzymes),
- rash,
- injection/infusion site reactions.

Less frequent side effects

- fungal superinfections,
- decreased appetite,

- hyperactivity, agitation, confusion, disorientation, hallucinations,
- eyesight problems including double vision,
- loss of hearing,
- rapid heartbeat (tachycardia),
- expansion of the blood vessels (vasodilation), low blood pressure,
- abdominal pain, digestive problems such as stomach upset (indigestion/heartburn), wind,
- liver disorders, increased amounts of one substance in the blood (bilirubin: you may notice that your skin and the whites of your eyes appear yellow, dark urine and feeling extremely tired), jaundice (cholestatic icterus),
- itching, hives,
- joint pain in adults,
- poor kidney function, kidney failure,
- pains in your muscles and bones, feeling unwell (asthenia), fever, fluid retention,
- increase in blood alkaline phosphatase (a certain substance in the blood),
- increased blood sugar (hyperglycaemia),
- decreased blood sugar (hypoglycaemia),
- anxiety reaction, strange dreams, depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide), mental disturbances (psychotic reactions potentially leading to thoughts of suicide, suicide attempts, or completed suicide),
- decreased skin sensitivity, tremor, migraine, disorder of sense of smell (olfactory disorders),
- tinnitus, impaired hearing,
- fainting, inflammation of the blood vessel (vasculitis),
- shortness of breath including asthmatic symptoms,

- hepatitis, death of liver cells (liver necrosis) which may lead to life-threatening liver failure,
- sensitivity to light, pin-point bleeding under the skin (petechiae),
- blood or crystals in the urine, urinary tract inflammation,
- visual colour distortions.

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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of FLOQIN IV 2mg/mL.

5. How to store FLOQIN IV 2 mg/mL

Store all medicines out of reach of children.

Store at or below 25 °C.

The glass bottles must be stored in the outer carton until required for use.

Your doctor, nurse or pharmacist knows how to store FLOQIN IV 2 mg/mL. The healthcare professional who is administering FLOQIN IV 2 mg/mL to you will make sure that the medicine is not used after the expiry date printed on the vial. They will also reconstitute FLOQIN IV 2 mg/mL and visually inspect the solution before giving it to you. Only clear solution without particles will be used.

Protect from light.

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 FLOQIN IV 2 mg/mL contains

- The active substance is ciprofloxacin.

  Each FLOQIN IV 2 mg/mL contains ciprofloxacin lactate equivalent to 2,0 mg ciprofloxacin per mL in 0,9 % sodium chloride solution.

- The other ingredients are:

  lactic acid

  sodium chloride

  water for injection

What FLOQIN IV 2 mg/mL looks like and contents of the pack

Clear, colourless to slightly yellowish solution, free from foreign matters or particles.

FLOQIN IV 200 mg/100 mL:

Uncoloured glass bottles type I, stoppered with bromobutyl rubber closures sealed with aluminium caps. One glass bottle is packaged in an outer carton.

FLOQIN IV 400 mg/200 mL:

Uncoloured glass bottles type I, stoppered with bromobutyl rubber closures sealed with aluminium caps. One glass bottle is packaged in an outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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