PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CIPROFLOXACIN 2 mg/mL (50 mL) FRESENIUS

CIPROFLOXACIN 2 mg/mL (100 mL) FRESENIUS

CIPROFLOXACIN 2 mg/mL (200 mL) FRESENIUS

Solution for infusion

Sugar free

Read all of this leaflet carefully before you are given CIPROFLOXACIN FRESENIUS

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

What is in this leaflet

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

1. What CIPROFLOXACIN FRESENIUS is and what it is used for

CIPROFLOXACIN FRESENIUS is an antibiotic belonging to the fluoroquinolone family. The active substance is ciprofloxacin and works by killing bacteria that cause infections. It only works with specific strains of bacteria.

CIPROFLOXACIN FRESENIUS is used in adults to treat severe and/or complicated bacterial infections of the lower respiratory tract (lungs), urinary tract (kidneys or bladder), skin and soft tissue, gastrointestinal tract (stomach or intestines), or bone.

2. What you need to know before you receive CIPROFLOXACIN FRESENIUS

You should not be given CIPROFLOXACIN FRESENIUS:

- If you are hypersensitive (allergic) to ciprofloxacin, any other quinolones, or any of the inactive ingredients (listed in section 6).
- If you are taking other medicines that result in abnormal heart rate and/or rhythm tracing (ECG) e.g. QT time prolongation.
- If you have or you are born with any condition with abnormal heart rhythm whether related to QT time prolongation or not (seen on electrical recording of the heart (ECG)).
- If you are pregnant or breastfeeding your baby.
- If you have a muscle disorder called myasthenia gravis (abnormal muscle fatigue, muscle weakness leading to paralysis in severe cases), and if alternative appropriate antibiotic choices are available.
- If you also take tizanidine (a medicine used to relax the muscles).
- 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 disorders).
- If you have an enlargement or “bulge” of a large blood vessel (aortic aneurysm) or a previous episode of a tear in the aortic wall (aortic dissection) or a family history of aortic aneurysm/dissection or other risk factors or predisposing conditions, and if alternative appropriate antibiotic choices are available.

- If you have confirmed mitral valve/aortic heart valve which cannot close properly (leakage of blood backward through the valve) unless no safer appropriate antibiotic is available, has failed or is not well tolerated.
- If you take high blood pressure medicines of the angiotensin-converting enzyme (ACE) inhibitors /angiotensin receptor blockers type. If you are unsure, ask your doctor.
- **If you are younger than 18 years of age.**

Warnings and precautions

Tell your doctor or healthcare provider before being given CIPROFLOXACIN FRESENIUS if you:

- have ever had kidney problems as your doctor may need to adjust the dose
- suffer from epilepsy or other neurological conditions, such as fits (see “You should not be given CIPROFLOXACIN FRESENIUS”)
- have a history of tendon problems during previous treatment with antibiotics such as CIPROFLOXACIN FRESENIUS (see “You should not be given CIPROFLOXACIN FRESENIUS”)
- have a muscle disorder called myasthenia gravis (see “You should not be given CIPROFLOXACIN FRESENIUS”)
- have heart problems. Tell your doctor 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 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 “You should not be given CIPROFLOXACIN FRESENIUS” and “Other medicines and CIPROFLOXACIN FRESENIUS”)

- have a damaged mitral and/or aortic heart valve which cannot close properly, i.e. leaking heart valves (heart valve regurgitation)
- have a family history of aortic aneurysm or aortic dissection or congenital heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan Syndrome, Ehlers-Danlos syndrome, Turner syndrome, Sjögren's syndrome (an inflammatory autoimmune disease), or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure or known atherosclerosis, rheumatoid arthritis (a disease of the joints) or endocarditis (an infection of the heart)) (see "You should not be given CIPROFLOXACIN FRESENIUS")
- have, or ever had depression or other mental health problems (see "You should not be given CIPROFLOXACIN FRESENIUS")
- have a genetic disorder that affect your red blood cells, called glucose-6-phosphate dehydrogenase deficiency
- are a diabetic
- are currently taking other medicines that can reduce your blood potassium levels.

Tell your doctor immediately, if any of the following occurs while receiving CIPROFLOXACIN FRESENIUS. Your doctor will decide whether treatment with CIPROFLOXACIN FRESENIUS 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 receiving CIPROFLOXACIN FRESENIUS and contact your doctor immediately.
- Severe skin reactions, called severe cutaneous adverse reactions (SCARs), which could be life-threatening or fatal, including conditions such as toxic epidermal necrolysis

(TEN), Stevens Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS).

If you notice signs and symptoms of severe skin reactions, stop receiving CIPROFLOXACIN FRESENIUS and contact your doctor immediately.

- If you feel sudden, severe pain in your abdomen, chest or back, which can be symptoms of aortic aneurysm and dissection, go to an emergency room immediately. Your risk may be increased if you are being treated with systemic corticosteroids.
- If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.
- Pain and swelling in the joints and tendons may occur (inflammation of your ligaments), 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 CIPROFLOXACIN FRESENIUS therapy. At the first sign of any pain or inflammation, stop receiving CIPROFLOXACIN FRESENIUS 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 CIPROFLOXACIN FRESENIUS may not occur (see “You should not be given CIPROFLOXACIN FRESENIUS”).
- If you suffer from epilepsy or other neurological conditions such as cerebral ischaemia or stroke, you may experience side effects associated with the central nervous system. If this happens, stop receiving CIPROFLOXACIN FRESENIUS and contact your doctor immediately (see “You should not be given CIPROFLOXACIN FRESENIUS”).
- You may experience mental health problems (psychiatric reactions) the first time you receive CIPROFLOXACIN FRESENIUS. If you suffer from depression or psychosis,

your symptoms may become worse under treatment with CIPROFLOXACIN FRESENIUS. Depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, stop receiving CIPROFLOXACIN FRESENIUS and contact your doctor immediately (see “You should not be given CIPROFLOXACIN FRESENIUS”).

- You may experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness in your limbs. If this happens, stop receiving CIPROFLOXACIN FRESENIUS 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 CIPROFLOXACIN FRESENIUS may not occur (see “You should not be given CIPROFLOXACIN FRESENIUS”).
- CIPROFLOXACIN FRESENIUS 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 receiving CIPROFLOXACIN FRESENIUS and contact your doctor immediately.
- Diarrhoea may develop while you are on CIPROFLOXACIN FRESENIUS, or even several weeks after you have stopped receiving it. If the diarrhoea becomes severe or persistent, or you notice that your stool contains blood or mucous, stop receiving CIPROFLOXACIN FRESENIUS and contact your doctor immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements.
- Your skin may become more sensitive to sunlight or ultraviolet (UV) light when receiving CIPROFLOXACIN FRESENIUS. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.
- If your vision becomes impaired or if you experience any effects on your eyes, consult an eye specialist immediately.
- Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammation, tendon rupture, joint pain, pain in the limbs,

difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

At the first signs or symptoms of any serious adverse drug reaction, stop receiving CIPROFLOXACIN FRESENIUS immediately and contact your doctor for advice.

Receiving CIPROFLOXACIN FRESENIUS with food and drink

CIPROFLOXACIN FRESENIUS may be administered with or without food.

Other medicines and CIPROFLOXACIN FRESENIUS

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

Do not use CIPROFLOXACIN FRESENIUS together with medicines that contain tizanidine as it may cause effects such as low blood pressure and sleepiness (see “You should not be given CIPROFLOXACIN FRESENIUS”).

Make sure to inform your doctor if you take the following medicines:

- medicines that affect the way your heart beats: medicines that belong to the group of Class IA and III antidysrhythmics, tricyclic antidepressants, some antibiotics (macrolides), some antipsychotics (used for schizophrenia)
- anti-coagulants (prevent blood clots) which inhibits vitamin K (e.g. warfarin acenocoumarol, phenprocoumon or fluindione)
- methotrexate (treatment of certain types of cancer, psoriasis or rheumatism)
- theophylline (for breathing problems)

- clozapine (treatment of schizophrenia)
- ropinirole (treatment of Parkinson's disease)
- ciclosporin (for skin conditions, rheumatoid arthritis and in organ transplants)
- oral antidiabetic medicines (to lower blood sugar) mainly sulfonylureas, e.g. glibenclamide, glimepiride (both for diabetes)
- insulin (used in diabetes to lower blood sugar)
- agomelatine (an antidepressant)
- duloxetine (antidepressant medicines, diabetic nerve damage or incontinence)
- lidocaine (lignocaine) (anaesthetic use or heart conditions)
- sildenafil (a medicine used for erectile dysfunction and high blood pressure)
- nonsteroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen (for pain, fever or inflammation)
- caffeine (a stimulant)
- pentoxifylline (a medicine to treat circulation disorders)
- phenytoin (an antiseizure medicine)
- ACE inhibitors/angiotensin receptor blockers (medicines for high blood pressure). Ask your doctor if you are not sure
- probenecid
- zolpidem (for sleeping).

Interaction with tests

CIPROFLOXACIN FRESENIUS may interfere with the results of tests for tuberculosis (TB). Tell the doctor or laboratory staff that you are receiving CIPROFLOXACIN FRESENIUS if you have to provide a blood or urine sample for testing.

Pregnancy and breastfeeding

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 receiving CIPROFLOXACIN FRESENIUS.

Do not receive CIPROFLOXACIN FRESENIUS if you are pregnant or planning to become pregnant.

CIPROFLOXACIN FRESENIUS may cause damage to the cartilage of the fetus.

Do not receive CIPROFLOXACIN FRESENIUS if you are breastfeeding.

CIPROFLOXACIN FRESENIUS is excreted in breastmilk and may harm your baby.

Driving and using machinery

CIPROFLOXACIN FRESENIUS may affect your ability to drive or to use machinery.
You should not drive or operate machines until you know how CIPROFLOXACIN FRESENIUS affects you. If you have these side effects, you should not drive or use machinery.

CIPROFLOXACIN FRESENIUS contains sodium

CIPROFLOXACIN FRESENIUS contains sodium. This may be harmful to people on low sodium or low salt diet.

3. HOW TO RECEIVE CIPROFLOXACIN FRESENIUS

You will not be expected to give yourself CIPROFLOXACIN FRESENIUS. It will be given to you by a person who is qualified to do so.

CIPROFLOXACIN FRESENIUS will be administered to you as an infusion through a needle into a vein. The infusion duration is 60 minutes.

Your doctor will decide on the suitable dose and duration of the treatment based on the type and severity of the infection that you have.

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

You may show a skin reaction at the injection site. This will clear up once the infusion is completed.

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.

If you receive more CIPROFLOXACIN FRESENIUS than you should

Since your healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage, your doctor will treat the side effects symptomatically.

4. POSSIBLE SIDE EFFECTS

CIPROFLOXACIN FRESENIUS can have side effects.

Not all side effects reported for CIPROFLOXACIN FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CIPROFLOXACIN FRESENIUS, please consult your doctor, pharmacist or healthcare provider for advice.

If any of the following happens, stop receiving CIPROFLOXACIN FRESENIUS and tell your doctor immediately:

- allergic reactions which may include swelling of the skin and mucous membranes of the face, lips, tongue and throat, which may cause difficulty in breathing (angio-oedema)
- anaphylactic reaction/shock which is a severe sudden allergic reaction and is rapid in onset. Symptoms of anaphylactic reaction include dizziness (feeling dizzy, sick or faint or experiencing dizziness when standing up), tightness in the chest, loss of consciousness, difficulty in breathing, swelling of the face, lips, tongue, throat and airways (breathing tubes), blueness of the skin, low blood pressure, heart failure, and can result in death

- sudden, intense and persistent abdominal or back pain
- severe dizziness, fainting, fast or pounding heartbeats
- sudden pain, snapping or popping sound, bruising, swelling, tenderness, stiffness, or loss of movement in any of your muscles, ligaments or joints
- watery diarrhoea which may have blood in it
- confusion, hallucinations, depression, unusual thoughts or behaviour
- seizures/convulsions
- pale or yellowed skin, dark coloured urine, fever, weakness; urinating less than usual or not at all
- easy bruising or bleeding
- burning, tingling, pain or numbness, weakness or unusual pain in your body or hands and feet
- the first sign of any skin rash, no matter how mild; or severe skin reaction – fever, sore throat, swelling in your face or tongue, burning in your eyes, skin pain with a red or purple skin rash that spreads in the face or upper body with blistering and skin peeling.

These are very serious side effects. If you have them, you may have had a serious reaction to CIPROFLOXACIN FRESENIUS. You may need urgent medical attention.

Frequent side effects:

- nausea, diarrhoea, vomiting
- increase in transaminases (substance in blood)
- skin rash
- injection site reaction.

Less frequent side effects:

- yeast/mould superinfections, inflammation of the bowel linked to antibiotic use (antibiotic-related colitis)

- high concentration of a type of white blood cells (eosinophils), changes in blood count (leukopenia, anaemia, neutropenia, leucocytosis), increased or decreased amounts of blood platelets (thrombocytopenia or thrombocytaemia)
- a special type of anaemia due to red blood destruction (haemolytic anaemia)
- a drop in a type of white blood cells (agranulocytosis) or a dangerous drop in the number of red and white blood cells and platelets (pancytopenia) which may be life-threatening
- bone marrow depression, which may also be life-threatening
- allergic reaction, swelling (oedema) or rapid swelling of the skin and mucous membranes (angioedema), severe allergic reaction which may be life-threatening (anaphylactic shock), an allergic reaction (serum sickness-like reaction)
- loss of appetite (anorexia), blood glucose disorders: low blood sugar levels (hypoglycaemia), high blood sugar levels (hyperglycaemia)
- hyperactivity/agitation, confusion and disorientation, anxiety reactions, abnormal (strange) dreams, depression or hallucinations, mental disturbances (psychotic reactions) which may lead to self-harm, such as thoughts of suicide and attempted or completed suicide
- headache, dizziness, sleep problems (insomnia or nightmares), taste disorders, pins and needles (paraesthesia), disturbed sensation (dysesthesia) or reduced sensation (hypoesthesia), tremors, seizures including status epilepticus (prolonged or repeated fits or seizures without any recovery between attacks), vertigo, migraine, disturbed coordination, smell disorders, hyperesthesia (increased sensitivity to stimuli), or intracranial hypertension including pseudo tumour cerebri (pressure on the brain)
- visual disturbances (eyesight problems such as double vision), visual colour distortions
- tinnitus (ringing in the ears), loss of hearing, impaired hearing
- tachycardia (rapid heartbeat)

- vasodilatation (expansion of blood vessels), hypotension (low blood pressure), or syncope (fainting), inflammation of the walls of the blood vessels (vasculitis), inflammation of the blood vessels (phlebitis or thrombophlebitis)
- dyspnoea (shortness of breath) including asthmatic condition
- stomach and abdominal pain, indigestion/heartburn, flatulence (gas), pancreatitis (inflammation of the pancreas)
- increased bilirubin (substance in blood), hepatic impairment (liver disorders), jaundice, or non-infective hepatitis, liver necrosis very rarely progressing to life-threatening hepatic failure
- itching or hives, photosensitivity reactions (sensitivity to light), blistering (blistering of the skin), petechiae (small, pin-point bleeding under the skin), erythema multiforme, erythema nodosum (various skin eruptions, blisters, peeling or rashes), Stevens-Johnson syndrome or toxic epidermal necrolysis which may be life-threatening (severe allergic skin reactions)
- pain in the hands or feet, back pain, chest pain, joint pain, muscle pain (myalgia), arthritis (inflammation of the joints), or increased muscle tone and cramping, muscular weakness, tendinitis, tendon rupture predominantly Achilles tendon (especially of the large tendon at the back of the ankle), worsening of the symptoms of myasthenia gravis, a muscle weakness
- poor kidney function, kidney failure, blood in the urine (haematuria), crystals in the urine (crystalluria) or a type of urinary tract inflammation (tubule-interstitial nephritis)
- unspecific pain, fever or feeling unwell, unsteady walk (gait disturbance), excessive sweating
- increase in blood alkaline phosphatase, abnormal clotting (prothrombin) factor level or increased levels of the enzyme amylase (increased amylase)
- very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammation, tendon rupture, joint pain, pain in the limbs,

difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Side effects with an unknown frequency:

- syndrome associated with impaired water excretion and low levels of sodium (SIADH)
- coma because of low blood sugar levels (hypoglycaemic coma)
- overactive energy, mood, behaviour, and activity levels significantly different from your normal state of mind (mania)
- cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones
- skin reactions and organ dysfunction related to conditions called acute generalised exanthematous pustulosis (AGEP) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Ask your doctor if you are unsure
- increased International Normalised Ratio (INR) in patients treated with certain blood thinning medicines.

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, pharmacist or nurse. 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 CIPROFLOXACIN FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store CIPROFLOXACIN FRESENIUS

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light.
- Store the infusion bag/bottle pack in the outer container until ready to use.
- Do not refrigerate or freeze.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CIPROFLOXACIN FRESENIUS contains

The active substance is ciprofloxacin.

Each mL contains ciprofloxacin hydrogen sulphate equivalent to 2 mg ciprofloxacin.

The other ingredients are sodium hydroxide (for pH-adjustment), sodium chloride and water for injection.

What CIPROFLOXACIN FRESENIUS looks like and contents of the pack

CIPROFLOXACIN FRESENIUS is a clear, colourless to slightly yellow solution.

CIPROFLOXACIN FRESENIUS is packed into 2 separate packaging systems:

100 mL and 250 mL KabiPac polyethylene bottles (50 mL and 100 mL solution filled in 100 mL bottlepack® and 200 mL solution filled in 250 mL bottlepack®).

100 mL and 300 mL **free***flex*® (polypropylene) bags wrapped in an aluminium overpouch (50 mL and 100 mL solution filled in 100 mL bag and 200 mL solution filled in 300 mL bag).

Pack sizes: 1's and 10's.

Not all packs and pack sizes may be marketed.

Holder of the Certificate of Registration

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

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1685

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This leaflet was last revised in

11 October 2023

Registration numbers

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CIPROFLOXACIN 2 mg/mL (200 mL) FRESENIUS: 45/20.1.1/0799

Access to the corresponding Professional Information

The professional information will be printed and packed with the product.