Clean Proposed Patient Information Leaflet (PIL)

for Medicines for Human Use

SCHEDULING STATUS: S4

CIPRO UNIMED 250 (Film-coated tablet)

CIPRO UNIMED 500 (Film-coated tablet)

CIPRO UNIMED 750 (Film-coated tablet)

Ciprofloxacin

Sugar free

Read all of this leaflet carefully before taking CIPRO UNIMED

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CIPRO UNIMED 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 CIPRO UNIMED is and what it is used for

CIPRO UNIMED contains the active substance ciprofloxacin. CIPRO UNIMED is an antibiotic belonging to the fluoroquinolone family.

CIPRO UNIMED 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 CIPRO UNIMED

Do not take CIPRO UNIMED:

- If you are hypersensitive (allergic) to ciprofloxacin, fluoroquinolones or any of the other ingredients of CIPRO UNIMED (listed in section 6).
- If you are pregnant or breastfeeding your baby.
- CIPRO UNIMED should not be used in children under the age of 18 years.
- If you are also taking a muscle relaxing medicine called tizanidine.
- If you are also taking methotrexate, a medicine used to reduce your bodies immune response.
- If you are deficient in glucose-6-phosphate dehydrogenase due to an inherited illness.
- 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 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 have myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases, paralysis).
- 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).

Warnings and precautions

Take special care with CIPRO UNIMED:

- if you have a history of seizures, convulsive disorders or suffer from other neurological conditions, you might experience side effects associated with the central nervous system. If this happens, stop taking CIPRO UNIMED immediately, and contact your doctor,
- if you are using medicines that will cause your urine to become alkaline,
- if you have impaired liver or kidney function,
- if you have a history of tendon problems during previous treatment with antibiotics such as CIPRO UNIMED,
- if you have QT interval prolongation or congenital long QT syndrome which is an abnormality of the heart leading to a very fast heart beating which may lead to sudden loss of consciousness,
- if you have heart disorders such as heart failure, myocardial infarction or

bradycardia,

- if vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately,
- if you have ever had kidney problems, because your treatment might need adjustment,
- 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 CIPRO UNIMED),
- 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, CIPRO UNIMED can cause acute kidney injury (see Do not take CIPRO UNIMED),
- if you have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated (see Do not take CIPRO UNIMED),
- CIPRO UNIMED may interfere with the interpretation of diagnostic culture tests for tuberculosis,
- If you have a severe, sudden allergic reaction (an anaphylactic reaction/shock, angio-oedema e.g. tightness in the chest, feeling dizzy, sick or faint, or experiencing dizziness when standing up.) If this happens, stop taking CIPRO UNIMED and contact your doctor immediately,
- if you have pain and swelling in the joints and tendonitis, especially if you are elderly and on corticosteroid treatment. If you experience any inflammation or swelling, stop taking CIPRO UNIMED immediately. Avoid any unnecessary exercise, as this may cause tendon rupture,

- if you experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or muscle weakness. If this happens, stop taking CIPRO UNIMED and contact your doctor immediately,
- if you develop diarrhoea while you are on antibiotic treatment or post treatment. If it becomes severe or persistent, and you notice blood in your stool, stop taking CIPRO UNIMED immediately and contact your doctor,
- if you are taking blood or urinary samples, inform the doctor or laboratory staff,
- CIPRO UNIMED may cause liver damage. Symptoms of this include loss of appetite, jaundice (yellowing of the skin), dark urine, itching or tenderness of the stomach. If any of these occur, stop CIPRO UNIMED treatment and inform your doctor,
- CIPRO UNIMED may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as a sore throat/pharynx/mouth or urinary problems, inform your doctor immediately,
- if you or a family member is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), inform your doctor, since you may experience a risk of anaemia with CIPRO UNIMED,
- skin sensitivity to sunlight or ultraviolet (UV) light. If this occurs, avoid exposure to strong sunlight or artificial UV light such as sunbeds,
- if you experience psychiatric reactions the first time you take CIPRO UNIMED. If you suffer from depression or psychosis, your symptoms may become worse under treatment with CIPRO UNIMED. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide

attempts, or completed suicide. If this happens, contact your doctor immediately,

- CIPRO UNIMED may cause disturbances in blood sugar, including both a decrease in blood sugar below normal levels (hypoglycaemia) and an increase in blood sugar above normal levels (hyperglycaemia). Disturbances in blood sugar occurred usually in elderly diabetic patients, receiving concomitant treatment with oral antidiabetic medicines that lower blood sugar (e.g. glibenclamide) or with insulin. Loss of consciousness due to severe reduction in blood sugar (hypoglycaemic coma) has been reported. If you suffer from diabetes, your blood sugar should be carefully monitored,
- your doctor should advise you that if you experience any symptoms of severe skin reactions when taking this medicine, to immediately stop taking CIPRO UNIMED and inform him. Symptoms may include fever, severe rash and skin problems and all allergic reactions, as this could be serious. These could be caused by Severe cutaneous adverse reactions (SCARs) including toxic epidermal necrolysis (TEN), Stevens Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported with CIPRO UNIMED and which could be life-threatening or fatal.

Children and adolescents

Do not use CIPRO UNIMED you are under 18 years old (see Do Not Take CIPRO UNIMED).

Other medicines and CIPRO UNIMED

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

The following medicines are known to interact with CIPRO UNIMED. Using CIPRO UNIMED 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:

- tizanidine (for muscle spasticity in multiple sclerosis). CIPRO UNIMED may lead to a drop in blood pressure and sedation. Avoid taking these medicines together,
- 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,
- if you are on treatment with ACE inhibitors/angiotensin receptor blockers (ARBs) used to control your blood pressure, ask your doctor if you are not sure,
- concomitant use of fluoroquinolones and ACE inhibitors/angiotensin receptor blockers may precipitate acute kidney injury,
- medicines used to treat diabetes, such as oral antidiabetic tablets e.g. glibenclamide, concurrent treatment with CIPRO UNIMED may cause hypoglycaemia (low blood sugar) or insulin,
- medicines that can increase ability to get seizures such theophylline, nonsteroidal anti-inflammatory drugs (NSAIDs),
- medicines used to stop your blood from clotting such as vitamin K antagonists (e.g. warfarin, acenocoumarol, phenprocoumon or fluindione) or other oral anti-coagulants (to thin the blood). The use of

CIPRO UNIMED with anticoagulants such as warfarin may lead to a prolonged anticoagulant effect of these medicines and increase the chance of bleeding,

- probenecid (for gout),
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis),
- theophylline (for breathing problems), aminophylline and oxtriphylline (a medicine used for asthma) may cause and increase in the plasma concentrations. As a result, you may experience more theophylline-related side effects,
- olanzapine, clozapine (antipsychotics),
- ropinirole (for Parkinson's disease),
- phenytoin (for epilepsy),
- metoclopramide (for nausea and vomiting),
- ciclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation),
- zolpidem (for sleep disorders), may lead to an increase blood level of zolpidem, concurrent use is not recommended,

CIPRO UNIMED may increase the levels of the following medicines in your blood:

- xanthine derived products such as pentoxifylline (for circulatory disorders),
- caffeine,
- duloxetine (for depression, diabetic nerve damage or incontinence),
- lidocaine (for heart conditions or anaesthetic use),
- sildenafil (for erectile dysfunction), leads to two-fold increase of sildenafil blood levels, caution should be used if you are taking this medicine.

- agomelatine (for depression).

Some medicines reduce the effect of CIPRO UNIMED.

Tell your doctor if you take or wish to take:

- antacids,
- omeprazole,
- mineral supplements (e.g. calcium, magnesium, aluminium, iron),
- highly buffered medicine (e.g. didanosine tablets),
- sucralfate,
- a polymeric phosphate binder (e.g. sevelamer or lanthanum carbonate),
- medicines or supplements containing calcium, magnesium, aluminium or iron.

If these preparations are essential, take CIPRO UNIMED about two hours before or no sooner than four hours after them.

CIPRO UNIMED with food and drink

CIPRO UNIMED may be taken with meals or on an empty stomach. However, DO NOT take CIPRO UNIMED with dairy products (such as milk and yoghurt); calcium-fortified juices (such as orange juice) or mineral-fortified drinks when you take the tablets, as they may affect the absorption of the active substance.

Pregnancy and breastfeeding

CIPRO UNIMED should not be used if you are pregnant or when breastfeeding 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 health care provider for advice before taking this medicine.

Driving and using machines

CIPRO UNIMED may impair your ability to drive or to operate machinery, especially if you used alcohol concurrently. CIPRO UNIMED may make you feel less alert. Some neurological adverse events can occur. It is not always possible to predict to what extent CIPRO UNIMED 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 CIPRO UNIMED affects them.

3. How to take CIPRO UNIMED

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

- Always take CIPRO UNIMED exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not unsure.

In the treatment of infections caused by *Pseudomonas aeruginosa,* an aminoglycoside must be administered concomitantly.

The usual dosage range is 250 – 750 mg twice daily. The duration of treatment depends upon the severity of the infection, clinical response and bacteriological cultures.

Severe and or complicated infections of the lower respiratory tract:

750 mg twice daily.

In cystic fibrosis patients: 750 mg twice daily. The low body mass of these patients should, however, be taken into consideration when determining dosage (7,5 to 15 mg/kg/day).

Severe and/or complicated infections of the urinary tract:

500 mg twice daily.

Severe and/or complicated infections of the skin:

750 mg twice daily.

Severe and/or complicated infectious diarrhoea: 500 mg twice daily.

Severe and/or complicated bone infections:

750 mg twice daily.

Treatment may be required for 4 – 6 weeks or longer.

Elderly patients should be treated with the lowest possible dose.

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

Your doctor will tell you how long your treatment with CIPRO UNIMED will last. This will depend on the type of infection you have and how bad it is.

The tablet must be swallowed whole with plenty of liquid.

Do not chew the tablets because they do not taste nice.

Do try to take the tablets at around the same time every day.

CIPRO UNIMED may be taken with or without meals. Any calcium you take as part of a meal will not seriously affect uptake. However, do not take CIPRO UNIMED tablets with dairy products such as milk or yoghurt or with fortified fruit juices (e.g. calcium-fortified orange juice).

Do not stop taking this medication without discussing it with your doctor.

If you have the impression that CIPRO UNIMED is too strong or too weak, tell your doctor or pharmacist.

If you take more CIPRO UNIMED than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take any remaining tablets and the container with you and show the pack to the doctor.

You may experience the following symptoms:

- Dizziness
- Tremor
- Headache
- Tiredness
- Fits (seizures)
- Hallucinations
- Confusion
- stomach discomfort
- bloody urine
- kidney and liver complications

If you forget to take CIPRO UNIMED:

If you forget to take a dose, take it as soon as you remember. If it almost time for your next dose wait until then. Do not double the dose, to make up for forgotten individual doses.

If you stop taking CIPRO UNIMED

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.

If you have any further questions about the use of this medicine, ask your

doctor or pharmacist.

4. Possible side effects

CIPRO UNIMED can have side effects.

Not all side effects reported for this CIPRO UNIMED are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking while taking CIPRO UNIMED, please consult your healthcare provider for advice.

If any of the following happen, stop taking CIPRO UNIMED and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe sudden allergic reactions (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,
- a serious life-threatening skin rash, usually in the form of blisters or ulcers in the mouth, throat, nose, eyes and other mucous membranes such as genitals which may progress to widespread blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis),
- seizure,
- sudden severe pain in your chest, abdomen (tummy) or back,
- muscle weakness, inflammation of the tendons which could lead to rupture of the tendon, particularly affecting the large tendon at the back of the ankle (Achilles tendon),
- unusual feelings of pain, burning tingling, numbness or muscle weakness in the extremities (neuropathy),
- a drug reaction that causes rash, fever, inflammation of internal organs, haematologic abnormalities and systemic illness (DRESS Drug

Reaction with Eosinophilia and Systemic Symptoms, AGEP Acute Generalised Exanthematous Pustulosis),

- yellowing of the skin and eyes, dark urine, loss of appetite, itching, tender stomach and tiredness which may be symptoms of liver problems, jaundice (cholestatic icterus), hepatitis, or death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure,
- kidney failure, blood or crystals in the urine.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea,
- diarrhoea (running stomach).

Less frequent side effects:

- vomiting (throwing up),
- dyspepsia (indigestion),
- stomach pain,
- flatulence (wind),
- changes to the blood count (haemolytic anaemia, leukopenia, leukocytosis, neutropenia, anaemia), a drop in a type of white blood cells (agranulocytosis), a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal, bone-marrow depression which may also be fatal,
- allergic reaction, swelling (oedema), or rapid swelling of the skin and mucous membranes (angio-oedema) and allergic reaction called serum sickness-like reaction,

- general feeling of weakness and myalgia (muscle pain in back, chest, body), muscle cramps, inflammation of the tendons,
- decreased appetite, increased blood sugar (hyperglycaemia) which can cause you feeling thirsty and passing water more often than usual or decreased blood sugar (hypoglycaemia) which can cause you feeling weak or irritable, sweating and/or trembling,
- hyperactivity, feeling of being agitated, confusion, anxiety, abnormal dreams, depression (feeling of sadness or thinking of suicide), psychotic reactions, feeling of happiness and sadness,
- headache, dizziness, sleep disorders, taste disorders,
- disturbances in vision, double vision, colour vision,
- hearing problems, like tinnitus (ringing in ear) and temporary loss of hearing,
- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases),
- changes in the way your heart beats, rapid heartbeat (tachycardia), 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),
- pins and needles, unusual sensitivity to stimuli of the senses, decreased skin sensitivity, tremors, or giddiness,
- worsening of the symptoms of myasthenia gravis,
- sensitivity to light,
- fungal superinfections,
- a high concentration of eosinophils, a type of white blood cell,
- increased amounts of certain substances in the blood (transaminases and/or bilirubin),
- rash, itching, or hives,

- poor kidney function usually seen with less urine than is normal for you,
- crystalluria (crystals found in urine), kidney failure, infection in the kidneys, blood in the urine, urinary tract inflammation,
- expansion of blood vessels (vasodilation), low blood pressure (hypotension) which can cause you feeling faint, light-headed or dizzy, or fainting,
- shortness of breath, including asthmatic symptoms,
- increased levels of the enzyme amylase, transaminases, alkaline phosphatase,
- liver problems, hepatitis (inflammation of the liver), liver necrosis (sign of liver failure),
- migraine, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell (olfactory disorders), pressure on the brain (intracranial pressure and pseudotumor cerebri),
- inflammation of the wall of the blood vessels (vasculitis),
- severe abdominal pain (pancreatitis),
- small, pin-point bleeding under the skin (petechiae); various skin eruptions or rashes,
- asthenia (feeling of abnormal weakness or lack of energy), fever, sweating.

Frequency unknown:

- syndrome associated with impaired water excretion and low levels of sodium (SIADH),
- hypoglycaemic coma,
- mood state characterised by elevation (euphoria) and overactivity,
- influence on blood clotting (in patients treated with Vitamin K antagonists).

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

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 "**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 this CIPRO UNIMED**.**

5. How to store CIPRO UNIMED

- Store at or below 25 ºC.
- Do not use after the expiry date stated on the carton.
- Store in the original package ~~or container~~.
- Keep the blister pack in the outer carton.
- Do not store in a bathroom.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

Store all medicine out of reach of children.

6. Contents of the pack and other information

What CIPRO UNIMED contains:

The active substance is ciprofloxacin:

Each CIPRO UNIMED 250 film-coated tablet contains 291 mg ciprofloxacin hydrochloride equivalent to 250 mg ciprofloxacin.

Each CIPRO UNIMED 500 film-coated tablet contains 582 mg ciprofloxacin

hydrochloride equivalent to 500 mg ciprofloxacin.

Each CIPRO UNIMED 750 film-coated tablet contains 873 mg ciprofloxacin hydrochloride equivalent to 750 mg ciprofloxacin.

The other ingredients are:

Core:

Cellulose, microcrystalline; sodium starch glycollate (type A); povidone, silica, colloidal anhydrous; stearic acid; magnesium stearate; croscarmellose, sodium

Film:

Hypromellose, macrogol 6000, talc, titanium dioxide (E 171)

What CIPRO UNIMED looks like and contents of the pack

CIPRO UNIMED 250**:**

White, round tablets, with breaking notch on one side

Embossment: cip 250

Diameter: 11 ± 0.2 mm

CIPRO UNIMED 500**:**

White, oblong tablets, with breaking notch on both sides

Embossment: cip 500

Length: 19 ± 0.2 mm

Breadth: 8.0 ± 0.2 mm

CIPRO UNIMED 750**:**

White, oblong tablets, with breaking notch on both sides

Embossment: cip 750

Length: 22 ± 0.2 mm

Breadth: 8.7 ± 0.2 mm

CIPRO UNIMED 250:

The tablets are packed into clear PVC / aluminium blister strips containing 10 tablets each.

1 (10) blister strips to be packed into a carton i.e. 10 tablets per carton

CIPRO UNIMED 500:

The tablets are packed into clear PVC / aluminium blister strips containing 10 tablets each.

1 (10) blister strips to be packed into a carton i.e. 10 tablets per carton

CIPRO UNIMED 750:

The tablets are packed into clear PVC / aluminium blister strips containing 10 tablets each.

1 (10) blister strips to be packed into a carton i.e. 10 tablets per carton

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

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