Patient Information Leaflet

Information for the Patient about

MOFLOXX TABLETS

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

MOFLOXX 400 containing **moxifloxacin** 400 mg (Tablets)

Read all of this leaflet carefully before you start taking MOFLOXX.

- **Keep this leaflet; you may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **MOFLOXX 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 MOFLOXX CONTAINS:

The active substance in **MOFLOXX** tablets is moxifloxacin.

Inactive ingredients are corn starch, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry pink (containing hypromellose, red iron oxide, macrogol and titanium dioxide), and povidone.

Contains 93,6 mg lactose monohydrate per tablet

WHAT MOFLOXX IS USED FOR:

MOFLOXX is used for the treatment of a bacterial infection of the sinuses, airways, lungs (where the infection was contracted outside a hospital), female reproductive organs and severe infections inside the belly (abdomen) where therapy with other appropriate antibiotics have failed, cannot be used or cannot be tolerated, specifically, the following infections:

- Acute bacterial sinusitis (infection of the sinuses).
- Acute worsening of chronic bronchitis due to a bacterial infection.
- Pneumonia (lung infection) of mild to moderate severity.
- Skin and soft tissue infections.
- Pelvic inflammatory disease (infections of the upper female genital tract)
- Complicated intra-abdominal infections (group of infections that located within the stomach area).

Your doctor will decide whether or not your infection qualifies for treatment with **MOFLOXX**. He/she may decide to take swabs or to perform blood tests to see whether the bacteria causing your infection are sensitive to **MOFLOXX**. Treatment with **MOFLOXX** may start before the results of these tests are known; however, your doctor may alter your treatment depending on these test results.

BEFORE YOU USE MOFLOXX:

Do NOT take MOFLOXX:

- If you are known to be allergic to moxifloxacin, any other component of the tablets or to any other quinolone antibiotics.
- **If you or your child are younger than 18 years of age.**

- If you are pregnant or breastfeeding (see **"Pregnancy and breastfeeding"**).
- 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 rhythm whether related to QT time prolongation or not (seen on ECG, electrical recording of the heart).
- If you have recently been diagnosed with electrolyte disturbances, such as low blood potassium levels.
- If you have any heart disease, especially heart failure or any disease affecting the blood supply to your heart (also known as coronary heart disease, ischaemic heart disease, heart attack or angina).
- If you are taking other medicines that result in abnormal heart rate or rhythm tracing (ECG) e.g. (prolongation of the “QT time”).
- If you suffer from liver problems.
- If you have moderate to severe impairment of your kidney function and are treated with ACE inhibitors/angiotensin receptor blockers. Ask your doctor if you are not sure.
- 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 have other risk factors or existing predisposing conditions.

- If you have mitral valve or aortic valve regurgitation (when your heart's mitral or aortic valve does not close tightly, causing blood to flow back into the heart instead of pumping out).

Take special care with MOFLOXX:

The presence of other medical conditions may affect the use of **MOFLOXX**. Tell your doctor or pharmacist if you have any of the following conditions as you may require a lower dose or special monitoring:

- Any condition that requires the use of medicines that may slow down your heart rate, such as cisapride, erythromycin (another antibiotic), antipsychotic medication (for the treatment of psychosis), antidepressants or medicines for irregular heart beat (e.g. disopyramide, amiodarone or sotalol) (see **"Do NOT take MOFLOXX if you"** and **"Taking other medicines with MOFLOXX"**).
- If you are currently taking other medicines that can reduce blood potassium levels (see **"Do NOT take MOFLOXX if you"** and **"Taking other medicines with MOFLOXX"**). You should inform your doctor of any other medicines that you are taking, including over-the-counter medicines, before you start taking **MOFLOXX**.
- Any personal or family history of heart problems / conditions.
- Convulsions, or epileptic seizures or fits since treatment with **MOFLOXX** may lead to convulsions in certain patients (see **Do not take MOFLOXX)**.
- Any central nervous system disorder, such as reduced blood flow to the brain due to atherosclerosis. Treatment with **MOFLOXX** may cause central nervous system (CNS) events, including dizziness, confusion,

tremors, hallucinations (hearing voices or seeing things that are not real), depression, anxiety, sleeplessness, nightmares or paranoia, agitation, nervousness and rarely suicidal thoughts or acts. You may experience some of these reactions following the first dose of **MOFLOXX**. If you experience any of these adverse reactions, you should immediately report them to your doctor.

- If you have been diagnosed with or have a history of any psychiatric disease, as you may develop psychiatric reactions even after the first dose of **MOFLOXX** (see **Do not take MOFLOXX)**. In some people depression or psychotic reactions have progressed to suicidal thoughts and self-injurious behaviour, such as suicide attempts (see **"POSSIBLE SIDE-EFFECTS"**). If you develop these reactions, treatment with **MOFLOXX** should be stopped. Your doctor may prescribe alternative medicine(s).
- Allergic reactions to other antibiotics, especially if you had an allergic reaction to other fluoroquinolone antibiotics. Symptoms of an allergic reaction may include hives, itching, skin rash, shortness of breath, swelling of the lips, tongue or throat, and tingling, and may progress to loss of consciousness, severely low blood pressure and even death. Some patients have experienced allergic reactions after the first dose of **MOFLOXX**. You should immediately report to your doctor if you develop a skin rash or any other sign of an allergic reaction, such as those listed here.
- If you have been diagnosed with myasthenia gravis (an inborn autoimmune disorder of the muscles) (see **“Do Not Take Mofloxx”**).

- If you are elderly and have any kidney problems. You should maintain adequate fluid intake because dehydration may increase your risk of kidney failure. You should take **MOFLOXX** with or without meals, and drink plenty of fluids.
- If you have been diagnosed with or have a family history of glucose-6-phosphate dehydrogenase deficiency (an inborn condition).
- If you have a family history of aortic aneurysm or aortic dissection or other risk factors or 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 Mofloxx"**).
- **MOFLOXX** may interfere with the interpretation of diagnostic culture tests for tuberculosis.
- If you have moderate to severe impairment of your kidney function, or if you are elderly and are treated with ACE inhibitors/angiotensin receptor blockers to control your blood pressure as this may cause further injury to your kidneys (see "**Do Not Take Mofloxx**").

Treatment with antibiotics, including **MOFLOXX**, may lead to the development of conditions known as antibiotic-associated diarrhoea (loose stools) and antibiotic-associated colitis, including pseudomembranous colitis, which cause an overgrowth of bacteria in the colon that are not sensitive to **MOFLOXX**. This condition is characterised by offensive-smelling diarrhoea (watery and severe), which may be bloody, severe stomach pain or cramps, fever, and loss of appetite. You should immediately report these symptoms to your doctor.

Another potentially serious complication of treatment with **MOFLOXX** is the development of tendon disorders, such as inflammation of a tendon (also known as tendinitis) or tendon rupture. This may develop from 2 to 42 days after the start of treatment with **MOFLOXX**. In the elderly and with concurrent use of corticosteroids the risk of tendon disorders may increase. If you experience pain, swelling, or redness over a tendon you should refrain from exercise and immediately report to your doctor.

You should inform your doctor if you experience pain, burning, tingling, numbness or weakness while taking **MOFLOXX**, as these may be symptoms of a nerve condition and your doctor may decide to prescribe alternative medicine(s) for you (see **"POSSIBLE SIDE EFFECTS"**).

You should contact your doctor if you develop weakness, yellow discolouration of the skin or whites of the eyes with or without pain over the liver area, dark urine, or bleeding tendency, as this may be due to liver disease, which may be life-threatening (see **"POSSIBLE SIDE EFFECTS"**). Your doctor may decide to monitor your liver function (see **"Do NOT take MOFLOXX if you"**).

Tell your doctor if you have been diagnosed with mitral valve or aortic valve regurgitation (when your heart's mitral or aortic valve does not close tightly, causing blood to flow back into the heart instead of pumping out). Your doctor will perform a thorough examination of your heart, including an echocardiogram,

since **MOFLOXX** should not be taken if you have mitral valve or aortic valve regurgitation (see **"Do not take MOFLOXX"**).

If you develop any blister-forming skin rash, or blisters on mucus membranes, you should report to your doctor immediately (see **"POSSIBLE SIDE-EFFECTS"**).

If you develop poor or blurred vision, you should consult an eye specialist immediately (see **"POSSIBLE SIDE EFFECTS"**).

Treatment with **MOFLOXX** may interfere with biological tests used in the diagnosis of certain diseases and cause false negative test results.
Please also note that treatment with **MOFLOXX** may lead to:

- Electrocardiogram (ECG) changes.
- Dizziness, palpitations and fainting spells, which you should report to your doctor immediately. Women and the elderly may be more sensitive to these effects and therefore special caution is required.
- The development of a skin rash or discolouration on sun exposed areas (known as phototoxicity or photosensitivity). In keeping with good medical practice, you should avoid excessive sunlight or artificial ultraviolet light (e.g. tanning beds). If sunburn-like reactions or skin eruptions occur, contact your doctor.

Taking MOFLOXX with food, and drink:

MOFLOXX can be taken without regard to meals since absorption of the active ingredient is not altered by the intake of food or dairy products.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, you should not use MOFLOXX (please see "Do NOT take MOFLOXX if you"). Based on results from animal studies, it seems that **MOFLOXX** may damage the cartilage (lining of the joints) of your unborn baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MOFLOXX.

Driving or using machinery:

MOFLOXX may make you feel dizzy or light-headed. If you experience dizziness or light-headedness, you should not drive a car or operate machinery.

Important information about some of the ingredients of MOFLOXX:

MOFLOXX contains lactose. If you are lactose intolerant, please speak to your doctor or pharmacist before taking **MOFLOXX**, as you may experience unwanted side-effects, such as nausea, cramping, bloating, diarrhoea, and flatulence after ingestion of **MOFLOXX**. If you have been diagnosed with rare inborn problems

of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption you should not take **MOFLOXX**.

Taking other medicines with MOFLOXX:

Always tell your healthcare professional if you are taking any other medicine.

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

In particular, tell your doctor if you are taking:

- Medicines that may slow down your heart rate. You should NOT take **MOFLOXX** with any of the following (see **"Do NOT take MOFLOXX if you"**):
    - Medicines for irregular heart beat or heart rhythm disorders, e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide or ibutilide.
    - Medicines for the treatment of psychosis, e.g. phenothiazines, pimozide, sertindole, haloperidol or sultopride.
    - Antidepressants, e.g. amitriptyline, trimipramine or desimipramine.
    - Antibiotics, e.g. saquinavir, sparfloxacin, erythromycin, pentamidine, or halofantrine (for malaria).
    - Antihistamines for allergic conditions, e.g. astemizole or mizolastine.

    - Cisapride or diphemanil for acid reflux.
    - Vincamine IV to increase blood flow to the brain.
    - Bepridil for heart conditions.
    - Medicines that reduce your blood pressure such as atenolol valsartan, losartan, enalapril, perindopril and captopril.
- Medicines that may reduce blood potassium levels (see **"Take special care with MOFLOXX"**):
    - Furosemide or hydrochlorothiazide (water tablets / diuretics).
    - Laxatives and enemas (high doses).
    - Corticosteroids, such as prednisone and cortisone, to suppress the immune system.
    - Amphotericin B, an antifungal medicine.
- Any other medicine that may cause slow heart rate (see **"Take special care with MOFLOXX"**).
- Antacids, minerals and multivitamins, since concurrent use with **MOFLOXX** may result in impaired absorption of the active ingredient and thus lowering of plasma concentrations of moxifloxacin. Therefore, antacids, antiretroviral agents (for the treatment of HIV) and other preparations containing magnesium, aluminium and other minerals, such as iron, should be administered at least 4 hours before or 2 hours after intake of **MOFLOXX**.
- Antidiabetic medicines for the treatment of diabetes, since concurrent administration of **MOFLOXX** with glibenclamide may result in a decrease of approximately 21 % in the peak plasma concentrations of glibenclamide.

- Non-steroidal anti-inflammatory medicines for the treatment of pain and inflammation, since concurrent administration of a non-steroidal anti-inflammatory medicine with **MOFLOXX** may increase the risk of central nervous system stimulation and convulsions.
- Warfarin, used in thinning blood to prevent clots, as using **MOFLOXX** with warfarin may increase the activity of warfarin.
- If you are on treatment with ACE inhibitors/angiotensin receptor blockers used to control your blood pressure.

HOW TO TAKE MOFLOXX:

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

Always take MOFLOXX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The usual dose for **MOFLOXX** is 400 mg once daily with or without food for all indications. You should swallow the tablets whole with a glass of water.

Your doctor will decide how long treatment with **MOFLOXX** will last, based on the severity of the infection as well as the site of the infection. In general, antibiotic therapy should be used for 3 – 4 days after the signs and symptoms of the infection have cleared. Total duration of treatment usually varies between 5 and 14 days.

If you have the impression that the effect of **MOFLOXX** is too strong or too weak, tell your doctor or pharmacist.

If you take more MOFLOXX than you should:

In the event of overdosage (if you take too many tablets), or if someone else takes your medicine by mistake, you, or this other person, may experience any of the side-effects listed below. **In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.**

If you forget to take MOFLOXX:

Always take **MOFLOXX** as prescribed. If you miss a dose, take it as soon as you remember. However, if you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE EFFECTS:

MOFLOXX can have side effects.

Not all side effects reported for MOFLOXX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MOFLOXX, please consult your doctor, pharmacist or other healthcare professional for advice.

The most serious side effects resulting from treatment with **MOFLOXX**, which you should report to your doctor as a matter of urgency, include the following:

- Abnormal heart rhythm, presenting with fainting spells, palpitations, or dizziness (see **"Take special care with MOFLOXX"**).

- Allergic or hypersensitivity reactions that can lead to 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 (see **"Take special care with MOFLOXX"** for the symptoms of an allergic reaction).
- Convulsions or central nervous system reactions, such as hallucinations or personality changes, spasticity or rigidity, and agitation (see **"Take special care with MOFLOXX"**).
- Diarrhoea due to a condition known as pseudomembranous colitis (see **"Take special care with MOFLOXX"**).
- Inflammation of a tendon or tendon rupture (see **"Take special care with MOFLOXX"**).
- Easy bruising, bleeding from the gums, blood in the urine, or pinpoint red spots on your skin due to low platelet counts.
- Fever, chills, cough, sore throat, generally feeling unwell, and slow to heal infections due to low white cell counts.
- Poor vision or blurred vision.
- Difficulty breathing or shortness of breath.
- Yellow discolouration of the skin or whites of the eyes (jaundice), loss of appetite, nausea and vomiting, pain over the liver area, fever, and generally feeling unwell due to adverse effects on the liver.
- Blistering skin rashes that may or may not be part of an allergic reaction to **MOFLOXX**.
- Blood in the urine, difficulty passing urine, or pain with urination, due to adverse effects on the kidneys.

Check with your doctor or pharmacist as soon as possible if any of the following side-effects develop:

- Thrush, including oral or vaginal thrush.
- Depression, difficulty walking or coordinating movements, tremor, confusion, memory loss, difficulty talking, emotional lability, loss of sense of smell, abnormal thinking, or diminished sensitivity to skin stimulation.
- Dizziness or ringing in the ears.
- Taste loss or painful swallowing.
- Swelling of the feet or ankles, or sudden severe pain in your chest, abdomen (tummy) or back.
- Stomach pain or heartburn, loss of appetite, or regurgitation of food.
- Inflammation of the lips, mouth or tongue, and abnormal taste.
- Photosensitivity (see **"Take special care with MOFLOXX"**).
- Vaginal infection or inflammation presenting with itching, or a discharge.
- Dehydration caused by less intake of fluids and diarrhoea.

Check with your doctor or pharmacist as soon as possible if any of the following side-effects continue or become bothersome:

- Headache, loss of appetite, sleeplessness, nervousness, excessive sleepiness, anxiety, pins and needles, or abnormal dreams.
- Nausea, vomiting, dyspepsia (poor digestion with heartburn), stomach discomfort, dry mouth, tongue discolouration, and flatulence (gas).
- Itching or excessive sweating.
- Joint or muscle pain, muscle cramps, tiredness or fatigue, back pain, generally feeling unwell, and leg or pelvic pain.

In addition to these side-effects, treatment with **MOFLOXX** may also cause changes in certain blood parameters, such as bleeding time, blood lipids, liver enzymes, markers of kidney function, blood uric acid levels, blood glucose levels, and blood cell counts, including platelet counts.

Please tell your doctor or pharmacist of any undesirable affects you think may be due to **MOFLOXX**, especially if not mentioned in this leaflet.

STORAGE AND DISPOSING OF MOFLOXX:

Store at or below 30°C in a dry place, protected from light and moisture.

Keep blisters in the carton until required for use.

Do not use the medication after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

KEEP THIS MEDICINE OUT OF REACH OF CHILDREN.

PRESENTATION:

Supplied in PVC/PE/PVDC film, plain aluminium foil blister strips of 5 and 10 tablets packed in a carton.

IDENTIFICATION OF MOFLOXX:

Pink coloured, film-coated, capsule-shaped, biconvex tablets, plain on both sides.

REGISTRATION NUMBER:

44/20.1.1/1063

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

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