

Patient Information Leaflet
Information for the Patient about

TAVALOXX 250 (Tablets)

TAVALOXX 500 (Tablets)

TAVALOXX 750 (Tablets)

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

TAVALOXX 250 (Tablets)

TAVALOXX 500 (Tablets)

TAVALOXX 750 (Tablets)

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

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

The active substance is levofloxacin.

TAVALOXX 250: Each tablet contains levofloxacin hemihydrate equivalent to 250 mg levofloxacin.

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

TAVALLOXX 500: Each tablet contains levofloxacin hemihydrate equivalent to 500 mg levofloxacin.

Inactive ingredients are croscarmellose sodium, magnesium stearate, microcrystalline cellulose, Opadry yellow (hypromellose, titanium dioxide, macrogol and iron oxide yellow), povidone and starch.

TAVALLOXX 750: Each tablet contains levofloxacin hemihydrate equivalent to 750 mg levofloxacin.

Inactive ingredients are croscarmellose sodium, magnesium stearate, microcrystalline cellulose, Opadry white (hypromellose, titanium dioxide and macrogol), povidone and starch.

TAVALLOXX is sugar free.

WHAT TAVALLOXX IS USED FOR

- TAVALLOXX 250, 500 & 750 belong to a class of medicines called broad and medium spectrum antibiotics (antibacterial substances).
- TAVALLOXX 250, 500 & 750 are used to treat bacterial infections caused by micro-organisms susceptible to levofloxacin (i.e. community acquired pneumonia, sinusitis, complicated/uncomplicated urinary tract infections, complicated skin and skin structure infections etc.).

- TAVALOX 750 is used to treat hospital acquired pneumonia caused by micro-organisms susceptible to levofloxacin.

BEFORE YOU TAKE TAVALOX

Do not take TAVALOX:

- If you are a patient with known hypersensitivity to this medicine or any of its components.
- If you have epilepsy.
- If you have a history of tendon disorders related to fluoroquinolone administration.
- In children or adolescents.
- During pregnancy and lactation because animal studies have shown that levofloxacin may affect joint development in growing organisms.
- If you have kidney function impairment and are currently using medicine to lower your blood pressure, including angiotensin-converting enzyme (ACE) inhibitors (e.g. enalapril, lisinopril, captopril) or renin-angiotensin blockers (e.g. valsartan, losartan).
- 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 TAVALOX

Tell your doctor if you have any of the following as you may then require a lower dose or special precautions:

- Allergic reactions, which may include a skin rash, difficulty breathing, wheezing, hives, itching or swelling of the lips, tongue or whole body may occur with TAVALOX, sometimes after the first dose. If you experience any of these symptoms during treatment, report to your doctor immediately. You may be required to stop the treatment.
- Porphyria.
- If you have ever had a fit (seizure).
- If you ever had a problem with your tendons such as tendonitis that was related to treatment with a quinolone antibiotic, such as TAVALOX.
- If you have kidney problems.
- If you have heart problems or if you were born with or have a family history of prolonged QT-interval (seen on ECG, electrical recording of the heart), have a salt imbalance in the blood (especially low level of potassium or magnesium) have a history of heart attack, have a very slow heart rhythm, or are elderly, caution should be taken when taking quinolone antibiotics, such as TAVALOX.
- 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 (see **Do not take TAVALOX**).
- If you have a condition known as glucose-6-phosphate dehydrogenase deficiency.
- If you have been diagnosed with depression or any psychiatric disease, as you may develop psychiatric reactions even after the first dose of TAVALOX. In

some people such reactions have progressed to suicidal thoughts and self-endangering behaviour or suicide.

- If you have been diagnosed with myasthenia gravis.

TAVALOXX may affect your blood sugar (glucose) levels (see **POSSIBLE SIDE EFFECTS**). It may increase or decrease your blood sugar levels and is more likely to affect people that have been diagnosed with diabetes mellitus and are taking oral antidiabetic medicine(s) or are using insulin. Very high or low blood glucose levels may result in coma and death. If you have been diagnosed with diabetes mellitus, you (in conjunction with your doctor) will have to monitor your blood glucose levels carefully while you are taking TAVALOXX. Report to your doctor if you develop excessive hunger or thirst, frequent urination, blurred vision, fatigue, sweating, shaking or trembling, or if you feel faint or dizzy.

If you start having severe, bloody diarrhoea during or after treatment with TAVALOXX tell your doctor immediately. This could mean you have serious inflammation of your bowel which can sometimes occur after antibiotic treatment.

TAVALOXX should be discontinued if you experience burning, tingling, pain or numbness.

Urine tests may show “false-positive” results for strong painkillers called opiates in people taking TAVALOXX. If your doctor has prescribed a urine test, tell your doctor you are taking TAVALOXX.

TAVALLOXX may cause “false-positive” results for some tests used to test for the tuberculosis bacteria.

Whilst taking TAVALLOXX you are advised to stay out of strong sunlight and not to use a sun lamp as some patients may become more sensitive to light whilst taking TAVALLOXX and get a sunburn-like reaction.

Before you start taking TAVALLOXX, tell your doctor if you are taking blood pressure lowering medicines called ACE inhibitors (such as enalapril, lisinopril, perindopril), or renin-angiotensin receptor blockers (such as losartan, valsartan) as taking TAVALLOXX with these medicines may cause damage to your kidneys, especially if you have an existing kidney problem (see **Do not take TAVALLOXX**). If your doctor has approved the use of these medicines with TAVALLOXX your kidney function will be monitored before and during treatment.

If you experience blurred vision or other problems with your eyesight, you should report to your doctor immediately.

If you are taking TAVALLOXX for a lengthy period it can lead to overgrowth of non-responsive organisms. Consult your doctor to ensure appropriate action is taken.

Taking TAVALLOXX with food and drink

TAVALLOXX can be taken without regard to meals. Each tablet should be swallowed whole with fluid. Do not divide, crush, chew or place the tablets in water (see **HOW TO TAKE TAVALLOXX**).

Pregnancy and breastfeeding

The safety of TAVALLOXX in pregnancy and lactation has not been established. Thus use in pregnancy and lactation is contraindicated (see **Do not take TAVALLOXX**).

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

Use in children

Safety and efficacy in individuals below 18 years of age has not been established and as such is contraindicated (see **Do not take TAVALLOXX**).

Use in elderly

TAVALLOXX appears to pose no exceptional safety problems for healthy elderly patients.

Driving and using machinery

TAVALLOXX has not been shown to impair judgement, thinking or motor skills. Be cautious about operating hazardous machinery and driving until you are certain that the medicine does not affect you adversely.

Taking other medicines with TAVALLOXX

See **BEFORE YOU TAKE TAVALLOXX**.

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

If you are taking other medicines on a regular basis, use of this medicine with other medicines may cause undesirable interactions.

Please consult your doctor or pharmacist.

Do not take TAVALOXX at the same time as the following medicines, as it can affect the way TAVALOXX works:

- Iron tablets (for anaemia), zinc supplements, magnesium or aluminium-containing antacids (for acid or heartburn), or sucralfate (for stomach ulcers).

Please discuss the use of the following with your doctor or pharmacist as you may require a dose adjustment or special precautions:

- Theophylline used for asthma, as you are more likely to have a fit (seizure) if taken with TAVALOXX.
- Non-steroidal anti-inflammatory drugs (NSAIDs) used for pain and inflammation, such as ibuprofen, fenbufen, as you are more likely to have a fit (seizure).
- Certain medicines used for blood pressure, as it may lead to a condition called acute kidney injury (see **Take special care with TAVALOXX**).
- Probenecid used for gout and cimetidine used for ulcers and heartburn, as special care should be taken when taking these medicines with TAVALOXX, especially if you have kidney problems.
- Warfarin used to thin the blood, as you may be more likely to have a bleed. You may need to take regular blood tests to check how well your blood is clotting.

- Medicines known to affect the way your heart beats. This includes medicines used for abnormal heart rhythm, depression, psychiatric disorders and bacterial infections.

HOW TO TAKE TAVALLOXX

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

Always take TAVALLOXX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Please consult your doctor before abruptly discontinuing TAVALLOXX.

If you take more TAVALLOXX than you should

In the event of an overdose (if you take too many tablets), or if someone else has taken your medicine by mistake, you, or this other person, may experience confusion, dizziness, impairment of consciousness and convulsive seizures. General and supportive measures are recommended.

In the event of overdose, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take TAVALLOXX

Take TAVALLOXX as prescribed. If you miss a dose of this medicine, take it as soon as possible. However, if you do not remember the missed dose until the next day, 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

TAVALLOXX can have side effects. As with any medicine, TAVALLOXX may have unintended or undesirable effects.

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

- Swallowing or breathing problems, hives, itching, skin rash, swelling of the lips, tongue or face, or any other symptom you think may be due to an allergic reaction.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TAVALLOXX. 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:

- Those that occur less frequently:
 - Fits (seizures).
 - Pain and inflammation in your tendons or ligaments, which could lead to rupture. The Achilles tendon is affected most often.
 - Watery diarrhoea which may have blood in it, possibly with stomach cramps and a high temperature. These could be signs of a severe bowel infection.
 - Pain, swelling or redness over a tendon (e.g. the Achilles tendon), torn tendon.

- Muscle weakness (especially in patients diagnosed with myasthenia gravis).
- Those that occur with unknown frequency:
 - Loss of appetite, skin and eyes becoming yellow in colour, dark-coloured urine, itching or tender stomach. These may be signs of liver problems.
 - Shortness of breath.
 - Burning, tingling, pain and numbness.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Those that occur frequently:
 - Sleeping problems.
 - Headache, feeling dizzy.
 - Nausea, vomiting and diarrhoea.
- Those that occur less frequently:
 - Feeling stressed, feeling confused, feeling nervous, feeling sleepy, trembling, a spinning feeling.
 - Feeling depressed, abnormal dreams or nightmares, seeing or hearing things that are not there.
 - Changes in the way things taste, loss of appetite, stomach upset or indigestion, pain in your stomach area, feeling bloated, or constipation.
 - Sweating too much.
 - Problems with your eyesight or hearing.

- Unusual fast beating of your heart, awareness of your heartbeat or low blood pressure, chest pain, fainting spells, light-headedness, fatigue or shortness of breath with or without exercise, or coughing when lying down, or swollen ankles.
- Muscle weakness.
- Lowering of your blood sugar levels especially if you are diabetic.
- Fungal infections and fungal infections resistant to usual treatment.
- Those that occur with unknown frequency:
 - Pale or yellow skin, fever, sore throat and a general feeling of being unwell.
 - Increase in your blood sugar levels, especially if you are diabetic.
 - Risk of having suicidal thoughts or actions.
 - Temporary loss of vision.
 - Impairment or loss of hearing.
 - Difficulty breathing or wheezing.
 - Increased sensitivity of your skin to sun and ultraviolet light.

Not all side-effects reported for this medicine are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

STORAGE AND DISPOSING OF TAVALLOXX

Store all medicines out of reach of children.

Store below 25 °C. Protect from light.

Keep the blister strips in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF TAVALLOXX

TAVALLOXX 250: A carton containing transparent PVC and aluminium foil blister strips of 3, 5 or 10 tablets.

TAVALLOXX 500: A carton containing transparent PVC and aluminium foil blister strips of 5 or 10 tablets.

TAVALLOXX 750: A carton containing transparent PVC and aluminium foil blister strips of 5 or 10 tablets.

IDENTIFICATION OF TAVALLOXX

TAVALLOXX 250: Brownish pink, film-coated, oval, biconvex tablets, debossed '250' on one side and plain on the other side.

TAVALLOXX 500: Pale yellow, film-coated, oval, biconvex tablets, debossed '500' on one side and plain on the other side.

TAVALLOXX 750: White, film-coated, oval, biconvex tablets, debossed '750' on one side and plain on the other side.

REGISTRATION NUMBERS

TAVALOXX 250: 41/20.1.1/0007

TAVALOXX 500: 41/20.1.1/0008

TAVALOXX 750: 41/20.1.1/0009

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

CIPLA MEDPRO (PTY) LTD

Building 9

Parc du Cap

Mispel Street

Bellville

7530

RSA

DATE OF PUBLICATION OF THIS PATIENT LEAFLET

05 October 2007

Revised: 16 August 2020

TAVALOXX 250:

Namibia NS2 09/20.1.1/0026

Botswana S2 BOT0801440

TAVALOXX 500:

Namibia NS2 09/20.1.1/0025

Botswana **S2** BOT0801421

TAVALLOXX 750:

Namibia **NS2** 09/20.1.1/0024