PATIENT INFORMATION LEAFLET FOR

TAVALOXX

SCHEDULING STATUS: S4

TAVALOXX 250, levofloxacin 250 mg, Tablets.

TAVALOXX 500, levofloxacin 500 mg, Tablets.

TAVALOXX 750 , levofloxacin 750 mg, Tablets.

Levofloxacin

Sugar free

Read all of this leaflet carefully before you start taking TAVALOXX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TAVALOXX 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 TAVALOXX is and what it is used for
2. What you need to know before you take TAVALOXX
3. How to take TAVALOXX
4. Possible side effects
5. How to store TAVALOXX
6. Contents of the pack and other information.

1. What TAVALOXX is and what it is used for

- TAVALOXX (levofloxacin) belongs to a class of medicine known as broad and medium spectrum antibiotics (antibacterial substances used in a wide variety of bacteria).
- TAVALOXX is indicated for the treatment of 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.).
- TAVALOXX 750 tablets are used to treat hospital acquired pneumonia caused by micro-organisms susceptible to levofloxacin.

2. What you need to know before you take TAVALOXX

Do not take TAVALOXX:

- If you are hypersensitive (allergic) to levofloxacin or any of the other ingredients of TAVALOXX (listed in **section 6**).
- 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).

Warnings and precautions

Take special care with TAVALOXX:

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 TAVALOXX, 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 TAVALOXX.
- 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 TAVALOXX.
- 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 TAVALOXX**).
- 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 TAVALOXX. In some people such reactions have progressed to suicidal thoughts and self-endangering behaviour or suicide.
- If you have been diagnosed with myasthenia gravis.
- If you are elderly and are on corticosteroid medication.
- If you had an organ transplant.
- If you have a family history of vascular disease including aneurysm, Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, hypertension and atherosclerosis.

TAVALOXX may affect your blood sugar (glucose) levels (see **section 4**). 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 you doctor immediately. This could mean you have serious inflammation of your bowel which can sometimes occur after antibiotic treatment.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone/quinolone antibacterial medicines, including TAVALOXX, have been associated with very rare but serious side effects, some of them being long lasting (continuing for months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, depression, memory impairment, severe fatigue, and severe sleep disorders.

If you experience any of these side effects after taking TAVALOXX, immediately stop the treatment and contact your doctor prior to continuing treatment.

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.

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

Whilst taking TAVALOXX 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 TAVALOXX and get a sunburnt like reaction.

Before you start taking TAVALOXX, 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 TAVALOXX with these medicines may cause damage to your kidneys, especially if you have an existing kidney problem (see **Do not**

take TAVALOXX). If your doctor has approved the use of these medicines with TAVALOXX 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 TAVALOXX for a lengthy period, it can lead to overgrowth of non-responsive organisms. Consult your doctor to ensure appropriate action is taken.

Children and adolescents

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

Use in elderly

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

Other medicines and TAVALOXX

Always tell your health care provider if you are taking any other medicine. (This includes all 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 precaution:

- 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, for depression, for psychiatric disorders and for bacterial infections.

TAVALOXX with food, drink and alcohol

TAVALOXX tablets 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 **section 3**).

Pregnancy, breastfeeding and fertility

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 TAVALOXX.

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

Driving and using machines

TAVALOXX tablets have 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.

It is not always possible to predict to what extent TAVALOXX 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 TAVALOXX affects them.

3. How to take TAVALOXX

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

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

The usual dose is one tablet once or twice daily.

Your doctor will tell you how long your treatment with TAVALOXX will last.

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

If you take more TAVALOXX than you should

In the event of an overdosage (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 overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take TAVALOXX

Take TAVALOXX 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 make up for the forgotten individual doses.

If you stop taking TAVALOXX

Please consult your doctor before abruptly discontinuing TAVALOXX as your doctor will advise you on the tapered dose to minimise the risk of discontinuation symptoms.

4. Possible side effects

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

Not all side effects reported for TAVALOXX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TAVALOXX, please consult your health care provider for advice.

If any of the following happens, stop taking TAVALOXX 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 reaction to TAVALOXX. 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
- Severe skin rashes which may include blistering or peeling of the skin around your lips, eyes, mouth, nose and genitals. These may be signs of Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN).

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 of 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.

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 the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of TAVALOXX.

5. How to store TAVALOXX

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or 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.

6. Contents of the pack and other information

What TAVALOXX contains

The active substance is levofloxacin.

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

The other ingredients are croscarmellose sodium, magnesium stearate, microcrystalline cellulose, Opadry Pink (Hypromellose, titanium dioxide, macrogol and iron oxide red), povidone and starch.

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

The other ingredients are croscarmellose sodium, magnesium stearate, microcrystalline cellulose, Opadry Yellow (Hypromellose, titanium dioxide, macrogol and iron oxide yellow), povidone and starch.

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

The other ingredients are croscarmellose sodium, magnesium stearate, microcrystalline cellulose, Opadry White (Hypromellose, titanium dioxide and macrogol), povidone and starch.

What TAVALOXX looks like and contents of the pack

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

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

TAVALOXX 750: White, film-coated, oval, biconvex tablets, debossed ‘750’ on one side and plain on the other side.

TAVALOXX 250: Is packed in a carton containing transparent PVC/PVDC and aluminium foil blister strips of 3, 5 or 10 tablets.

TAVALOXX 500: Is packed in a carton containing transparent PVC/PE/PVDC and aluminium foil blister strips of 5 or 10 tablets.

TAVALOXX 750: Is packed in a carton containing transparent PVC/PVDC and aluminium foil blister strips of 5 or 10 tablets.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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TAVALOXX 750: 41/20.1.1/0009.

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Access to the corresponding Professional Information

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated and included after approval.