Professional Information for

TAVALOXX 250 / 500 / 750 TABLETS

SCHEDULING STATUS

S4

PROPRIETARY NAME (AND DOSAGE FORM)

TAVALOXX 250 (Tablets)

TAVALOXX 500 (Tablets)

TAVALOXX 750 (Tablets)

COMPOSITION

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.

TAVALOXX 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.

TAVALOXX 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.

TAVALOXX is sugar free.

PHARMACOLOGICAL CLASSIFICATION

A 20.1.1 - Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Levofloxacin is a broad spectrum bactericidal agent from the chemical group fluoroquinolone. Levofloxacin is the pure (-) – (S) – enantiomer of ofloxacin.

Mechanism of action

Levofloxacin's bactericidal action results from interference with the enzymes topoisomerase IV and DNA gyrase, which are needed for the DNA replication, transcription, repair and recombination.

Levofloxacin is bactericidal *in vitro.* Cross-resistance exists between levofloxacin and other fluoroquinolones *in vitro.* Generally there is no cross-resistance between levofloxacin and other classes of antibacterial agents, due to the mechanism of action of levofloxacin.

The antibacterial spectrum of levofloxacin covers many Gram-positive and Gram-negative bacteria. Levofloxacin can be used successfully against the following organisms:

Gram-negative organisms: *Acinetobacter calcoaceticus, Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Moraxella catarrhalis, Proteus mirabilis* and *Pseudomonas aeruginosa.*

Gram-positive organisms: *Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes* and *Streptococcus faecalis.*

Other organisms: *Chlamydia pneumoniae, Legionella pneumophila* and *Mycoplasma pneumoniae.*

Pharmacokinetic properties

Absorption

After oral administration levofloxacin is rapidly and almost completely absorbed with peak plasma concentrations being obtained within 1 hour. Food has little effect on the absorption of levofloxacin and the tablets may be taken during or between meals. The absolute bioavailability is approximately 100 %.

The absorption of levofloxacin is significantly reduced when administered with iron salts, antacids and sucralfate.

Levofloxacin obeys linear pharmacokinetics over a range of 50 – 1000 mg. Steady state conditions are reached after approximately 48 hours following levofloxacin 750 mg once daily dosage. Multiple doses of 750 mg once daily shows negligible accumulation.

Distribution

Levofloxacin is approximately 30 – 40 % bound to serum protein. The mean volume of distribution of levofloxacin is approximately 100 L after single and repeated 500 mg doses, indicating widespread distribution into body tissues.

Metabolism

Levofloxacin is metabolised to a small degree to inactive metabolites being desmethyllevofloxacin and levofloxacin-N-oxide. These metabolites account for < 5 % of the dose excreted in urine. Levofloxacin is stereochemically stable and does not undergo chiral inversion.

Excretion

The elimination half-life of levofloxacin is six to eight hours after oral and intravenous administration. Levofloxacin is excreted largely unchanged, primarily via the kidney The mean apparent total body clearance of levofloxacin following a 500 mg single dose is 175 ± 29,2 mL/min. There are no major differences in the pharmacokinetics of levofloxacin following intravenous and oral administration, suggesting that the oral and intravenous routes are interchangeable.

Distribution in tissues and fluids

Levofloxacin penetrates well into lung tissue, bone tissue, bronchial mucosa, epithelial lining fluid and blister fluid.

INDICATIONS

TAVALOXX can be used in adults, in the treatment of the following bacterial infections:

Acute exacerbations of chronic bronchitis: caused by *H. influenzae, K. pneumoniae, S. aureus, M. catarrhalis, E. coli, H. parainfluenzae* or *S. pneumoniae.*

Pneumonia (community-acquired): caused by *H. influenzae, S. pneumoniae, S. aureus, M. catarrhalis, H. parainfluenzae, K. pneumoniae, E. coli, Mycoplasma pneumoniae, Chlamydia pneumoniae* or *Legionella pneumophila.*

Sinusitis: caused *by H. influenzae, S. pneumoniae, S. aureus, M. catarrhalis* or *H. parainfluenzae.*

Urinary tract infections (complicated) and acute pyelonephritis: caused by *E. coli, K. pneumoniae, S. faecalis, P. mirabilis, Enterobacter cloacae* and *P. aeruginosa.*

Uncomplicated urinary tract infections in women: caused by *E. coli, K. pneumoniae.*

Skin and soft tissue infections (uncomplicated): caused by *S. aureus, S. pyogenes, Acinetobacter calcoaceticus, E. cloacae, P. mirabilis, P. aeruginosa, E. coli, K. pneumoniae* or *S. faecalis.*

Skin and soft tissue infections (complicated): caused by *S. aureus, S. pyogenes, P. mirabilis, E. coli, K. pneumoniae, S. faecalis, E. cloacae, K. oxytoca.*

Intra-abdominal infections: caused by to *E. coli* and anaerobic micro-organisms.

TAVALOXX 750:

Hospital acquired pneumonia: due to *H. influenzae, S. pneumoniae* and methicillin-sensitive *S. aureus.*

CONTRAINDICATIONS

The use of TAVALOXX is contraindicated in:

- Previous hypersensitivity reaction to levofloxacin, other quinolones, or any other ingredient.
- Epilepsy.
- Patients with history of tendon disorders associated with fluoroquinolone administration.
- Children or adolescents (under 18 years of age).
- Pregnancy and lactation.
- Patients with moderate to severe renal impairment who are using ACE inhibitors or renin-angiotensin blockers concomitantly.
- Patients with confirmed mitral valve and/or aortic valve regurgitation unless no safer appropriate alternative antibiotic is available, has failed or is not well tolerated.

WARNINGS AND SPECIAL PRECAUTIONS

TAVALOXX SHOULD NOT BE GIVEN TO PATIENTS UNDER 18 YEARS OF AGE.

Caution should be exercised when using TAVALOXX in patients:

- Prone to seizures, such as patients with pre-existing central nervous system

lesions.

- Being treated with fenbufen or non-steroidal anti-inflammatory medicines.
- Using medicines which lower the cerebral seizure threshold, such as theophylline.
- Driving or operating machinery, as the use of TAVALOXX may alter the ability to drive or to operate machinery.
- Being tested for tuberculosis as TAVALOXX inhibits the growth of *Mycobacterium tuberculosis* and therefore may give false-negative results in the bacteriological diagnosis of tuberculosis.
- Exposed to ultraviolet light such as sunlight through window glass or longer wavelength ultraviolet (UVA) from sunbeds, in order to prevent photosensitisation.

Disturbances in blood glucose, including both hyperglycaemia and hypoglycaemia have been reported, usually in diabetic patients receiving concomitant treatment with an oral hypoglycaemic medicine or with insulin. Cases of hypoglycaemic coma have been reported. In diabetic patients, careful monitoring of blood glucose is recommended (see **SIDE EFFECTS**).

Pseudomembranous colitis

Diarrhoea, particularly if severe, persistent and/or bloody, during or after treatment with TAVALOXX, may be symptomatic of pseudomembranous colitis due to *Clostridium difficile.* If pseudomembranous colitis is suspected, TAVALOXX must be stopped immediately (see **SIDE EFFECTS**).

Tendinitis

Tendinitis, which is observed with the use of quinolones, such as TAVALOXX, may occasionally lead to tendon rupture involving the Achilles tendon in particular. This effect may occur within 48 hours of starting treatment and may be bilateral. Elderly patients are more prone to tendinitis. The risk of tendon rupture may be increased by co-administration of corticosteroids. If tendonitis is suspected, treatment with TAVALOXX must be stopped immediately. Tendonitis / rupture may occur after several weeks after discontinuation of TAVALOXX (see **SIDE EFFECTS**).

Patients with renal impairment

Since TAVALOXX is excreted mainly by the kidneys, the dose of TAVALOXX should be adjusted in patients with renal impairment (see **DOSAGE AND DIRECTIONS FOR USE**).

Concomitant use of fluoroquinolones, such as TAVALOXX and ACE inhibitors / renin-angiotensin receptor blockers may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and elderly patients (see **CONTRAINDICATIONS** and **SIDE EFFECTS**). Renal function should be assessed before initiating treatment, with fluoroquinolones or ACE inhibitors / renin-angiotensin receptor blockers.

QT-interval prolongation

Caution should be taken when using fluoroquinolones, including TAVALOXX, in patients with known risk factors for prolongation of the QT-interval such as:

- The elderly.

- Uncorrected electrolyte imbalance (e.g. hypokalaemia, hypomagnesaemia).
- Congenital long QT syndrome.
- Cardiac disease (e.g. heart failure, myocardial infarction, bradycardia).
- Concomitant use of medicines that are known to prolong the QT-interval [e.g. Class IA and III antidysrhythmics, tricyclic antidepressants, macrolides, antipsychotics] (see **INTERACTIONS**).

Women and the elderly may be more sensitive to QTc-prolonging medicines. Therefore, caution should be taken when fluoroquinolones, including TAVALOXX, are administered in these populations.

Cardiac disorders

There is some evidence, although inconclusive, of a possible association between oral fluoroquinolone use, such as TAVALOXX, and mitral valve and/or aortic valve regurgitation. A thorough cardiovascular examination including an echocardiogram, should be performed before oral fluoroquinolones are prescribed. Fluoroquinolones, including TAVALOXX, should not be prescribed to patients with mitral valve and/or aortic valve regurgitation (see **CONTRAINDICATIONS**).

Glucose-6-phosphate dehydrogenase deficiency

Patients with latent or actual defects in glucose-6-phosphate dehydrogenase activity may be prone to haemolytic reactions when treated with quinolones, such as TAVALOXX. The potential occurrence of haemolysis should be monitored.

Peripheral neuropathy

Sensory or sensorimotor peripheral neuropathy has been reported in patients receiving fluoroquinolones, including TAVALOXX, which can be rapid in its onset. TAVALOXX should be discontinued if the patient experiences symptoms of neuropathy. This would minimise the possible risk of developing an irreversible condition (see **SIDE EFFECTS**).

In patients treated with TAVALOXX, determination of opiates in urine may give a false-positive result.

Methicillin resistant *S. aureus* (MRSA) is very likely to possess co-resistance to fluoroquinolones, including levofloxacin. Levofloxacin is not recommended for the treatment of known or suspected MRSA infections unless laboratory results have confirmed susceptibility of the organism to levofloxacin (and commonly recommended antibacterial agents for the treatment of MRSA-infections are not considered appropriate).

Resistance to fluoroquinolones of *E. coli* – the most common pathogen involved in urinary tract infections – varies. Prescribers are advised to consider the local prevalence of resistance in *E. coli* to fluoroquinolones.

Hypersensitivity reactions

Levofloxacin may cause serious, potentially fatal hypersensitivity reactions (e.g. angio-oedema up to anaphylactic shock), occasionally following the initial dose. Patients should discontinue treatment immediately and contact their doctor who will initiate appropriate emergency measures (see **SIDE EFFECTS**).

Severe bullous reactions

Severe bullous skin reactions such as Stevens-Johnson syndrome or toxic epidermal necrolysis have been reported with levofloxacin. Patients should be advised to contact their doctor immediately before continuing treatment if skin and/or mucosal reactions occur.

Psychotic reactions

Psychotic reactions have been reported in patients receiving quinolones, including levofloxacin. In very rare cases these have progressed to suicidal thoughts and self-endangering behaviour – sometimes after a single dose of levofloxacin. Levofloxacin should then be discontinued and appropriate measures instituted. Caution is therefore recommended if levofloxacin is indicated in psychotic patients or in patients with a history of psychiatric disease (see **SIDE EFFECTS**).

Hepatobiliary disorders

Hepatic necrosis up to fatal hepatic failure has been reported with levofloxacin, primarily in patients with severe underlying diseases, e.g. sepsis. Treatment should be stopped and patients should contact their doctor if signs and symptoms of hepatic disease develop such as anorexia, jaundice, dark urine, pruritus or tender abdomen.

Exacerbation of myasthenia gravis

Fluoroquinolones, such as levofloxacin, have neuromuscular blocking activity and may exacerbate muscle weakness in patients with myasthenia gravis.

Vision disorders

If vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately.

Superinfection

The use of levofloxacin, as in TAVALOXX, especially if prolonged, may result in overgrowth of non-susceptible organisms. If superinfection occurs during therapy, appropriate measures should be taken.

Effect on ability to drive and use machines

TAVALOXX may alter reactivity to such an extent that the ability to drive or to operate machinery may be impaired.

INTERACTIONS

The absorption of TAVALOXX is significantly reduced when administered with iron salts, antacids and sucralfate. It is recommended that preparations containing iron salts, sucralfate, magnesium- or aluminium-containing antacids should not be taken 2 hours before or after TAVALOXX tablet administration.

TAVALOXX is known to inhibit hepatic drug metabolism and may interfere with the clearance of medicines, such as theophylline, fenbufen or similar non-steroidal anti-inflammatory medicines that lower the seizure threshold.

Concomitant use of fluoroquinolones, such as TAVALOXX and ACE inhibitors / renin-angiotensin receptor blockers may precipitate acute kidney injury (see

CONTRAINDICATIONS). Careful consideration should be given to age, renal function, hydration status and concomitant prescribing of diuretics or NSAIDs, and to monitoring of changes in renal function throughout treatment.

Caution should be exercised when TAVALOXX is co-administered with medicines that affect tubular renal secretion, such as probenecid and cimetidine, especially in renally impaired patients.

Increased coagulation tests (PT / INR) and/or bleeding which may be severe, have been reported in patients treated with TAVALOXX in combination with a vitamin K antagonist (e.g. warfarin). Coagulation tests should be monitored in patients treated with vitamin K antagonists.

TAVALOXX should be used with caution in patients receiving medicines known to prolong the QT-interval [e.g. Class IA and III antidysrhythmics, tricyclic antidepressants, macrolides] (see **WARNINGS AND SPECIAL PRECAUTIONS**).

HUMAN REPRODUCTION

The use of TAVALOXX during pregnancy and lactation is contraindicated (see **CONTRAINDICATIONS**).

DOSAGE AND DIRECTIONS FOR USE

TAVALOXX tablets should be swallowed whole, without crushing. TAVALOXX tablets may be taken on an empty stomach or with meals. TAVALOXX is to be taken once or twice daily.

The dosage will depend on the type of pathogen and the severity of the infection. The use of TAVALOXX should be continued for a minimum of 48 to 72 hours after it has become evident that the patient has a bacterial infection. The duration of therapy varies according to the course of the disease.

The following daily dose is recommended for TAVALOXX:

Daily dosage recommended in patients with normal renal function

Bronchitis, bacterial exacerbations: 500 mg once daily for 5 – 10 days. Alternatively, 750 mg once daily for 3 to 5 days if caused by *H. influenzae*, methicillin-sensitive *S. aureus*, *M. catarrhalis*, *H. parainfluenzae* or *S. pneumoniae*.

Pneumonia, community acquired: 500 mg once or twice daily for 10 – 14 days (the higher dosage should be chosen in the presence of complicating factors e.g. co-morbidity, advanced age). Alternatively, 750 mg once daily for 5 days if caused by *H. influenzae, S. pneumoniae, H. parainfluenzae, M. pneumoniae, C. pneumoniae* or *L. pneumophila*.

Sinusitis: 500 mg once daily for 10 to 14 days. Alternatively, 750 mg once daily for 5 days.

Urinary tract infections (complicated) and acute pyelonephritis: 250 mg once daily for 10 days.

Urinary tract infections (uncomplicated) in women: 250 mg once daily for 3 days.

Uncomplicated skin and soft tissue infections: 250 to 500 mg once daily for 7 – 10 days.

Complicated skin and soft tissue infections: 500 mg once daily for 10 – 14 days.

Intra-abdominal infections: 500 mg once daily in combination with an antibiotic with anaerobic coverage for 10 - 14 days.

Above infections when bacteraemia or septicaemia is present: 500 mg twice daily for 10 – 14 days.

Hospital acquired pneumonia: 750 mg once daily for 10 to 14 days if caused by *H. influenzae, S. pneumoniae* and methicillin-sensitive *H. influenzae, S. pneumoniae* and methicillin-sensitive *S. aureus.*

Daily dosage recommended in patients with impaired renal function

Dosage must be adjusted in patients with impaired renal function according to the degree of impairment (creatinine clearance ≤ 50 mL/min):

Patients with a creatinine clearance between 20 and 50 mL/min

Patients to be taking 250 or 500 mg once daily: a normal single dose should be given initially and then reduced by half this dose once daily.

Patients to be taking 500 mg twice daily: the initial dose should be 500 mg and then 250 mg should be taken twelve hourly.

In patients meant to be taking 750 mg once daily: a normal single dose should be given initially, and then 750 mg should be administered every 48 hours.

Patients with a creatinine clearance between 10 and 19 mL/min

Patients to be taking 250 mg once daily: a normal single dose should be given initially and then reduced to 125 mg every 48 hours.

Patients to be taking 500 mg once daily: should be given a normal single dose initially and then this dose should be reduced to 125 mg every 24 hours.

Patients to be taking 500 mg twice daily: should be given 500 mg initially and then this dose should be reduced to 125 mg every 12 hours.

In patients meant to be taking 750 mg once daily: a normal single dose should be given initially, and then reduced to 500 mg administered every 48 hours.

Patients with a creatinine clearance of less than 10 mL/min or in patients on haemodialysis or CAPD (Continuous Ambulatory Peritoneal Dialysis)

In patients where the prescribed dosage is 250 mg once daily: a normal single dose should be given initially and then this dose should be reduced to 125 mg every 48 hours.

Patients to be taking 500 mg once daily: should be given a normal single dose initially and then this dose should be reduced to 125 mg every 24 hours.

Patients to be taking 500 mg twice daily: should be given 500 mg initially and then this dose should be reduced to 125 mg every 24 hours.

In patients meant to be taking 750 mg once daily: a normal single dose should be given initially, and then reduced to 500 mg administered every 48 hours.

No adjustment of dosage is required in the elderly or in patients with impaired liver function.

SIDE EFFECTS

The following side effects have been reported:

Infections and infestations

Less frequent: Fungal infection, pathogen resistance, fungal overgrowth and proliferation of other resistant micro-organisms.

Blood and the lymphatic system disorders

Less frequent: Leukopenia, eosinophilia, neutropenia, thrombocytopenia.

Frequency unknown: Pancytopenia, agranulocytosis, haemolytic anaemia.

Immune system disorders

Less frequent: Angio-oedema, allergic manifestations, hypersensitivity, pruritus, rash, urticaria, vasculitis reactions.

Frequency unknown: Anaphylactic shock, anaphylactoid shock.

Metabolism and nutrition disorders

Less frequent: Hypoglycaemia, particularly in diabetic patients (see **WARNINGS AND SPECIAL PRECAUTIONS**), anorexia.

Frequency unknown: Hyperglycaemia, hypoglycaemic coma.

Psychiatric disorders

Frequent: Insomnia.

Less frequent:	Anxiety, confusional state, psychotic disorder (with e.g. hallucination) depression, agitation, nervousness, abnormal dreams, nightmares.
Frequency unknown:	Psychotic disorders with self-endangering behaviour including suicidal ideation or suicide attempt.

Nervous system disorders

Frequent:	Headache, dizziness.
Less frequent:	Somnolence, tremor, dysgeusia, paraesthesia, convulsion.
Frequency unknown:	Peripheral sensory neuropathy, peripheral sensory motor neuropathy, parosmia including anosmia, dyskinesia, extrapyramidal disorder, ageusia, syncope, benign intracranial hypertension.

In the event of such adverse reactions, TAVALOXX must be discontinued immediately and the medical practitioner informed.

Eye disorders

Less frequent:	Visual disturbances (such as blurred vision).
Frequency unknown:	Transient vision loss, uveitis.

Ear and labyrinth disorders

Less frequent:	Vertigo, tinnitus.
Frequency unknown:	Hearing impaired, hearing loss.

Cardiac disorders

Less frequent: Tachycardia, palpitation.

Frequency unknown: Ventricular tachycardia, which may result in cardiac arrest, ventricular arrhythmia and torsade de pointes (predominantly in patients with risk factors for QT prolongation, electrocardiogram QT prolonged.

Vascular disorders

Less frequent: Hypotension.

Respiratory, thoracic and mediastinal disorders

Less frequent: Dyspnoea, allergic pneumonitis.

Frequency unknown: Bronchospasm.

Gastrointestinal disorders

Frequent: Nausea, diarrhoea, vomiting.

Less frequent: Gastrointestinal symptoms may occur (gastric or abdominal symptoms, loss of appetite, abdominal pain, dyspepsia, flatulence, constipation). The onset of diarrhoea, particularly if severe, persistent and/or bloody, during or after treatment with TAVALOXX, may indicate the appearance of pseudomembranous colitis. Suspicion of pseudomembranous colitis requires immediate cessation of treatment with appropriate specific antibiotic therapy.

Hepatobiliary disorders

Frequent:	Hepatic enzyme increased (ALT / AST, alkaline phosphatase, GGT).
Less frequent:	Blood bilirubin increased.
Frequency unknown:	Jaundice and severe liver injury, including cases with fatal acute liver failure, primarily in patients with severe underlying diseases.

Skin and subcutaneous tissue disorders

Less frequent:	Rash, pruritus, urticaria, hyperhidrosis.
Frequency unknown:	Toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, photosensitivity reaction, leukocytoclastic vasculitis, stomatitis.

Musculoskeletal, connective tissue and bone disorders

Less frequent:	Arthralgia, myalgia, tendon disorder including tendinitis (e.g. Achilles tendon), muscular weakness which may be of special importance in patients with myasthenia gravis.
Frequency unknown:	Rhabdomyolysis, tendon rupture (e.g. Achilles tendon, ligament rupture, muscle rupture, arthritis.

Renal and urinary disorders

Less frequent:	Blood creatinine increased, renal failure acute (e.g. due to interstitial nephritis.

General disorders and administrative site conditions

Less frequent:	Asthenia, pyrexia (fever), disturbances of taste and smell, fungal overgrowth and proliferation of other resistant micro-organisms.
Frequency unknown:	Pain (including pain in back, chest and extremities).

TAVALOXX is known to possibly trigger attacks of porphyria in patients suffering from porphyria.

Post-marketing

Metabolism and nutrition disorders

Frequency unknown:	Hyperglycaemia, hypoglycaemic coma (see **WARNINGS AND SPECIAL PRECAUTIONS**).

Cardiac disorders

Frequency unknown:	Cases of mitral valve and/or aortic valve regurgitation were reported in patients treated with oral fluoroquinolones, such as TAVALOXX. Due to insufficient post-marketing information in the reported cases, it is unknown whether fluoroquinolone use was the causative factor, or a contributory factor or played no role in the reported cases where mitral and/or aortic regurgitation cases was diagnosed.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

According to studies in animals, the most important signs to be expected following acute overdosage of TAVALOXX are central nervous system symptoms such as confusion, dizziness, impairment of consciousness and convulsive seizures, increases in QT-interval as well as gastro-intestinal reactions such as nausea and mucosal erosions. The treatment of an overdosage is only symptomatic and supportive.

TAVALOXX is not effectively removed by haemodialysis or peritoneal dialysis.

In the event of overdose the patient should be carefully observed (including ECG monitoring) and symptomatic treatment should be implemented. In case of acute oral overdosage, gastric lavage should also be considered and antacids may be used for protection of gastric mucosa.

IDENTIFICATION

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.

PRESENTATION

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

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

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

STORAGE INSTRUCTIONS

Store below 25 °C. Protect from light.

Keep the blisters in the outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

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 OF THE CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD

Building 9

Parc du Cap

Mispel Street

Bellville

7530

RSA

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TAVALOXX 250:

Namibia NS2 09/20.1.1/0026
Botswana S2 BOT0801440

TAVALOXX 500:

Namibia NS2 09/20.1.1/0025
Botswana S2 BOT0801421

TAVALOXX 750:

Namibia NS2 09/20.1.1/0024