LINOX 600

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for LINOX 600 [Linezolid Tablets I.P. 600 mg]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Linezolid is a synthetic, antibacterial agent that belongs to a new class of antimicrobials, the oxazolidinones. It has *in vitro* activity against aerobic Gram positive bacteria and anaerobic micro-organisms. Linezolid selectively inhibits bacterial protein synthesis via a unique mechanism of action. Specifically, it binds to a site on the bacterial ribosome (23S of the 50S subunit) and prevents the formation of a functional 70S initiation complex which is an essential component of the translation process.

INDICATIONS: For the treatment of osteomyelitis in adults; for the treatment of complicated/uncomplicated skin & skin structure infection, community acquired pneumonia.

DOSAGE AND ADMINISTRATION: As directed by the Physician. The recommended linezolid dosage should be administered orally twice daily. Route of administration: Oral use. The film-coated tablets may be taken with or without food.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Linezolid should not be used in patients taking any medicinal product which inhibits monoamine oxidases A or B or within two weeks of taking any such medicinal product. Unless there are facilities available for close observation and monitoring of blood pressure, linezolid should not be administered to patients with the following underlying clinical conditions or on the following types of concomitant medications: - Patients with uncontrolled hypertension, phaeochromocytoma, carcinoid, thyrotoxicosis, bipolar depression, schizoaffective disorder, acute confusional states. - Patients taking any of the following medications: serotonin re-uptake inhibitors, tricyclic antidepressants, serotonin 5-HT1 receptor agonists (triptans), directly and indirectly acting sympathomimetic agents (including the adrenergic bronchodilators, pseudoephedrine and phenylpropanolamine), vasopressive agents (e.g. epinephrine, norepinephrine), dopaminergic agents (e.g. dopamine, dobutamine), pethidine or buspirone. Animal data suggest that linezolid and its metabolites may pass into breast milk and, accordingly, breastfeeding should be discontinued prior to and throughout administration.

WARNINGS & PRECAUTIONS: If significant myelosuppression occurs during linezolid therapy, treatment should be stopped unless it is considered absolutely necessary to continue therapy, in which case intensive monitoring of blood counts and appropriate management strategies should be implemented. In complicated skin and soft tissue infections linezolid should only be used in patients with known or possible co-infection with Gram negative organisms if there are no alternative treatment options available. In cases of suspected or verified antibiotic-associated colitis, discontinuation of linezolid may be warranted. Appropriate management measures should be instituted. If lactic acidosis occurs, the benefits of continued use of linezolid should be weighed against the potential risks. Linezolid inhibits mitochondrial protein synthesis Co-administration of linezolid and serotonergic agents is therefore contraindicated except where administration of linezolid and concomitant serotonergic agents is essential. If peripheral or optic neuropathy occurs, the continued use of Linezolid should be weighed against the potential risks. Patients should be advised to inform their physician if they have a history of seizures. Linezolid is not recommended for use in these circumstances unless close observation and monitoring of the recipient is possible. Patients should be advised against consuming large amounts of tyramine rich foods. The tablets contain lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

DRUG INTERACTIONS: There are very limited data from drug interaction studies and on the safety of linezolid when administered to patients on concomitant medications that might put them at risk from MAO inhibition. In normotensive healthy volunteers, linezolid enhanced the increases in blood pressure caused by pseudoephedrine and phenylpropanolamine hydrochloride. During clinical use of linezolid with serotonergic agents, including antidepressants such as selective serotonin reuptake inhibitors (SSRIs), cases of serotonin syndrome have been reported. This suggests that it is only necessary to avoid ingesting excessive amounts of food and beverages with a high tyramine content.

ADVERSE REACTIONS: Candidiasis, oral candidiasis, vaginal candidiasis, fungal infections, vaginitis, antibiotic associated colitis, including pseudomembranous colitis, leucopenia, neutropenia, thrombocytopenia, eosinophilia, myelosuppression, pancytopenia, anaemia, sideroblastic anaemia, anaphylaxis, lactic acidosis, hyponatraemia, insomnia, headache, taste perversion (metallic taste), dizziness, hypoaesthesia, paraesthesia, serotonin syndrome, convulsions, peripheral neuropathy, blurred vision, optic neuropathy, optic neuritis, loss of vision, changes in visual acuity, changes in colour vision, changes in visual field defect, tinnitus, arrhythmia (tachycardia), hypertension, phlebitis, thrombophlebitis, transient ischaemic attacks, diarrhoea, nausea, vomiting, pancreatitis, gastritis, localised or general abdominal pain, constipation, dry mouth, dyspepsia, glossitis, loose stools, stomatitis, tongue discolouration or disorder, superficial tooth discolouration, abnormal liver function test; increased AST, ALT or alkaline phosphatase, increased total bilirubin, urticaria, dermatitis, diaphoresis, pruritus, rash, bullous disorders such as those described as Stevens-Johnson syndrome and toxic epidermal necrolysis, angioedema, alopecia, increased bun, polyuria, increased creatinine, renal failure, vulvovaginal disorder, chills, fatigue, fever, injection site pain, increased thirst, localised pain, increased LDH, creatine kinase, lipase, amylase or non-fasting glucose. decreased total protein, albumin, sodium or calcium. increased or decreased potassium or bicarbonate, increased neutrophils or eosinophils, decreased haemoglobin, haematocrit or red blood cell count. increased or decreased platelet or white blood cell counts, increased sodium or calcium. decreased non fasting glucose. increased or decreased chloride, increased reticulocyte count, decreased neutrophils.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)