

TEDIREX 200

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

Abbreviated Prescribing information for TEDIREX [Tedizolid Phosphate Tablets 200 mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Tedizolid is an antibacterial drug. The antibacterial activity of tedizolid is mediated by binding to the 50S subunit of the bacterial ribosome resulting in inhibition of protein synthesis. Tedizolid inhibits bacterial protein synthesis through a mechanism of action different from that of other non-oxazolidinone class antibacterial drugs; therefore, cross-resistance between tedizolid and other classes of antibacterial drugs is unlikely. The results of in vitro time-kill studies show that tedizolid is bacteriostatic against enterococci, staphylococci, and streptococci.

INDICATIONS: Tedizolid is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults and adolescents 12 years of age and older.

DOSAGE AND ADMINISTRATION: The recommended dosage for adults and adolescents 12 years of age and older is 200 mg once daily for 6 days. Patients should be informed that Tedizolid tablets may be taken with or without food and without any dietary restrictions.

CONTRAINDICATION: Hypersensitivity to Tedizolid or any of its components.

WARNINGS & PRECAUTIONS: Tedizolid inhibits mitochondrial protein synthesis. Adverse reactions such as lactic acidosis, anaemia and neuropathy (optic and peripheral) may occur as a result of this inhibition. Thrombocytopenia decreased haemoglobin and decreased neutrophils have been observed during treatment with tedizolid phosphate. Patients who develop myelosuppression should be monitored and the benefit-risk should be reevaluated. All patients should be advised to report symptoms of visual impairment, such as changes in visual acuity, changes in colour vision, blurred vision, or visual field defect. Tedizolid phosphate should be administered with caution in patients known to be hypersensitive to other oxazolidinones since cross-hypersensitivity may occur. Clostridioides difficile associated diarrhoea (CDAD) has been reported for tedizolid phosphate. CDAD may range in severity from mild diarrhoea to fatal colitis. Prescribing tedizolid phosphate in the absence of a proven or strongly suspected bacterial infection increases the risk of the development of drug-resistant bacteria. Tedizolid is generally not active against Gram-negative bacteria.

DRUG INTERACTIONS: In a clinical study comparing the single dose (10 mg) pharmacokinetics of rosuvastatin (Breast Cancer Resistant Protein [BCRP] substrate) alone or in combination with tedizolid phosphate (once-daily 200 mg oral dose), rosuvastatin AUC and C_{max} increased by approximately 70% and 55%, respectively, when coadministered with tedizolid phosphate. Therefore, orally administered tedizolid phosphate can result in inhibition of BCRP at the intestinal level.

ADVERSE REACTIONS: Nausea, headache, diarrhea, vomiting, dizziness, anemia, palpitations, tachycardia, asthenopia, vision blurred, visual impairment, vitreous floaters, drug hypersensitivity, Clostridioides difficile colitis, oral candidiasis, vulvovaginal mycotic infection, hepatic transaminases increased (ALT increased, AST increased), gamma-glutamyltransferase (GGT) increased, white blood cell count decreased, hypoesthesia, paresthesia, VIIth nerve paralysis, insomnia, pruritus, urticaria, dermatitis, flushing, hypertension and thrombocytopenia.

MARKETED BY:



Torrent Pharmaceuticals Limited.

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(Additional information is available on request)