

Tezo™

Tedizolid Phosphate 200 mg

Composition:

Tezo™ Tablet: Each film coated tablet contains Tedizolid Phosphate INN 200 mg.

Pharmacology:

Tedizolid phosphate is an oxazolidinone antibiotic prodrug which inhibits bacterial protein synthesis in its active form by binding to the 50s subunit of the bacterial ribosome. It has shown in vitro activity against *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* group (including *Streptococcus anginosus*, *Streptococcus intermedius* and *Streptococcus constellatus*), and *Enterococcus faecalis*.

Indication:

Tedizolid tablets are indicated for the treatment of acute bacterial skin and skin structure infection by susceptible isolates of Gram-positive microorganisms.

Dose & Administration:

The recommended dosage of Tedizolid tablet is 200 mg orally, administered once daily for six (6) days, with or without food in patients 18 years of age or older.

Contraindication: None

Warning and Precaution:

In an animal model, the antibacterial activity of Tedizolid phosphate was reduced in the absence of granulocytes. Alternative therapies should be considered when treating patients with neutropenia and acute bacterial skin and skin structure infection. *Clostridium difficile* – associated diarrhea (CDAD) has been reported for nearly all systemic colitis. Treatment with antibacterial agents can alter the normal flora of the colon and may permit overgrowth of *C. difficile*.

Side Effects:

Common: Nausea, headache, diarrhea, vomiting, and dizziness.

Rare: Dermatitis, pruritus, urticaria, tachycardia, dehydration, heart burn etc.

Use in Pregnancy & Lactation:

Pregnancy Category C. There are no adequate and well controlled studies of Tedizolid phosphate in pregnant women. So, it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Tedizolid excreted in human milk.

Use in Children & Elderly:

Pediatric Use: Safety & effectiveness in pediatric patients below the age of 18 have not been established.

Geriatric Use: Clinical studies of Tedizolid did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. No overall differences in pharmacokinetics were observed between elderly subjects and younger subjects.

Drug Interaction:

Tedizolid phosphate inhibits or induces the metabolism of selected CYP enzyme. No potential drug interaction with Tedizolid phosphate were identified in in vitro CYP inhibition or induction studies. These results suggest that drug-drug interaction based on oxidative metabolism are unlikely. Tedizolid phosphate is reversible inhibitor of monoamine oxidase (MAO) in vitro. Orally administered Tedizolid inhibits Breast Cancer Resistance Protein (BCRP) in the intestine, which can increase the plasma concentrations of orally administered BCRP substrates, and the potential for adverse reactions.

Overdose:

Tedizolid should be discontinued and general supportive treatment given. Hemodialysis does not result in meaningful removal of Tedizolid from systemic circulation.

Storage:

Store below 30° C. Keep all medicines out of the reach of children.

Packing:

Tezo™ Tablet: Each box contains 6 tablets in blister pack .

Manufactured by



SQUARE
PHARMACEUTICALS PLC.

Bangladesh