

Composition:

Tedibac™ 200 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*.

Indications:

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

Dose and administration:

200 mg tablet administered once daily for 6 days.
Or as directed by the Physician.
Route of Administration: Oral

Contra-indications:

None

Warning and precaution:

In an animal model of infection, 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 (may affect up to 1 to 10 people).
Rare: Dermatitis, pruritus, urticaria, tachycardia, dehydration, heart burn etc.

Use in pregnancy & lactation:

There are no adequate and well controlled studies of Tedizolid phosphate in pregnant women and lactating mother.

Use in children & adolescents:

Safely & effectiveness in pediatric patients below the age of 12 have not been established.

Drug interaction:

Tedizolid phosphate detectably inhibited or induced the metabolism of selected CYP enzyme substrates. 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. The interaction with MAO inhibitors could not be evaluated in phase 2 and 3 trials, as subjects taking such medications were excluded from the trials.

Before meal or after meal: Can be taken.

Overdose:

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

Storage:

Store in a cool and dry place below 25°C, protect from light. Keep out of the reach of children.

Packing:

Tedibac™ 200 Tablet: Each box contains 6 tablets in a blister pack.