Tezolid™

Tedizolid Phosphate 200 mg

Presentation

Tezolid™ Tablet: Each tablet contains Tedizolid Phosphate INN 200 mg.
Tezolid™ IV Infusion: Each vial contains Tedizolid Phosphate INN 200 mg as lyophilized powder for IV infusion.

Description

Tedizolid is an oxazolidinone-class antibiotic indicated for the treatment of acute bacterial skin and skin structure infections caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant and methicillin-susceptible isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*) and *Enterococcus faecalis*.

Indication and uses

Tedizolid is indicated in adults for the treatment of acute bacterial skin and skin structure infections.

Dosage and administration

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

The recommended dosage and administration is described in table-

Indication	Route	Dosage	Frequency	Infusion time	Duration of treatment
Acute Bacterial Skin and Skin Structure Infection	Oral	200 mg	Once daily	Not aplicable	6 days
	IV	200 mg	Once daily	1 hour	

No dose adjustment is necessary when changing from intravenous to oral Tedizolid.

If patients miss a dose, they should take it as soon as possible anytime up to 8 hours prior to their next scheduled dose. If less than 8 hours remain before the next dose, wait until their next scheduled dose.

Safety and effectiveness in pediatrics patients below the age of 18 have not been established.
No overall differences in pharmacokinetics were observed between elderly subjects and younger subjects.

Method of reconstitution of IV infusion

The contents of the vial should be reconstituted using aseptic technique as follows:

Note: To minimize foaming, avoid vigorous agitation or shaking of the vial during or after reconstitution.

1. Reconstitute the Tedizolid vial with 4 ml of normal saline from the bottle with the syringe.
2. Gently swirl the contents and let the vial stand until the cake has completely dissolved and any foam disperses.

3. Inspect the vial to ensure the solution contains no particulate matter and no cake or powder remains attached to the sides of the vial. If necessary, invert the vial to dissolve any remaining powder and swirl gently to prevent foaming. The total storage time should not exceed 24 hours at either room temperature or under refrigeration at 2°C to 8°C .

4. The reconstituted solution must be further diluted by rest of the normal saline. Invert the bag gently to mix. Do not shake the bag as this may cause foaming.

After reconstitution and dilution, Tedizolid is to be administered via intravenous infusion using a total time of 1 hour.

Compatible infusion fluid

Tedizolid is compatible with normal saline (0.9% Sodium Chloride Injection, USP).

Contraindications

Tezolid is contraindicated in patients who have known hypersensitivity to Tedizolid or any other components of Tezolid.

Side effects

The most common side effects in patients treated with Tedizoild are nausea, headache, diarrhea, vomiting and dizziness.The following selected adverse reactions may be reported in Tedizolid treated patients: anemia, palpitations, tachycardia, blurred vision, visual impairment, infusion-related reactions, drug hypersensitivity, insomnia, pruritus, urticaria, dermatitis, hypertension etc.

Precautions

Alternative therapies should be considered when treating patients with neutropenia and acute bacterial skin and skin structure infection, *Clostridium difficile*-associated diarrhea and the risk of the development of drug-resistant bacteria.

Pregnancy and lactation

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

Drug interactions

No potential drug interactions with Tedizolid were identified in vitro CYP inhibition or induction studies. No clinically significant inhibition of any transporter was observed at Tedizolid circulating plasma concentrations up to the C_{max}. Tedizolid is a reversible inhibitor of monoamine oxidase in vitro.

Overdosage

Tedizolid should be discontinued and general supportive treatment given.

Pharmaceutical precautions

Administer Tezolid IV infusion as an intravenous infusion only. The intravenous bag containing the reconstituted and diluted intravenous solution should be inspected visually for particulate matter prior to administration. After reconstitution and dilution, it is to be administered via intravenous infusion using a total time of 1 hour. The total time from reconstitution to administration should not exceed 24 hours at room temperature or under refrigeration at 2°C to 8°C.

Commercial pack

Tezolid™ Tablet: Each box contains 2 blister strips of 3 tablets.
Tezolid™ IV Infusion: Each pack contains 1 vial of lyophilized powder of Tedizolid Phosphate INN 200 mg, 1 bottle of 250 ml normal saline with hanger, 1 syringe and 1 infusion set.

Manufactured by
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