

Celutis™

Tedizolid Phosphate 200 mg Tablet

Composition

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

Pharmacology

Celutis™ is a prodrug that is converted by phosphatases to Tedizolid, the microbiologically active moiety, following oral and intravenous administration. Following multiple once-daily oral or intravenous administration, steady-state concentrations are achieved within approximately three days with **Celutis™**, accumulation of approximately 30% (**Celutis™** half-life of approximately 12 hours). Peak plasma **Celutis™** concentrations are achieved within approximately 3 hours following oral administration under fasting conditions. The absolute bioavailability is approximately 91% and no dosage adjustment is necessary between intravenous and oral administration. Protein binding of **Celutis™** to human plasma proteins is approximately 70 to 90%. Other than Tedizolid Phosphate, which accounts for approximately 95% of the total radiocarbon AUC in plasma, there are no other significant circulating metabolites in humans. There was no degradation of **Celutis™** in human liver microsomes indicating Tedizolid Phosphate is unlikely to be a substrate for hepatic CYP450 enzymes. Following single oral administration of 14C-labeled Tedizolid Phosphate under fasted conditions, the majority of elimination occurred via the liver, with 82% of the radioactive dose recovered in feces and 18% in urine.

Indications

Celutis™ is an oxazolidinone-class antibacterial indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) 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*.

Dosage and Administration

Celutis™ is recommended in patients with 18 years of age or older. **Celutis™** should be administered 200 mg once daily for six (6) days orally (with or without food).

If patients miss a dose, they should take it as soon as possible at 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.

Contraindications

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

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.

Side Effects

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

Use in Pregnancy & Lactation

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

Use in Children & Adolescents

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

Drug Interactions

No potential drug interactions with **Celutis™** were identified in vitro CYP inhibition or induction studies. No clinically significant inhibition of any transporter was observed at Tedizolid Phosphate circulating plasma concentrations. Tedizolid Phosphate is a reversible inhibitor of monoamine oxidase in vitro.

Overdose

Tedizolid Phosphate should be discontinued & general supportive treatment given.

Storage

Store in a cool (below 30°C) and dry place, away from light. Keep out of the reach of children.

Packing

Celutis™ Tablet: Each box contains 2 blister packs with each blister of 3 tablets.

Manufactured by:

 **GENERAL**
Pharmaceuticals Ltd.

Mouchak, Kaliakair, Gazipur, Bangladesh

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