

Teconin™

Teicoplanin BP

Composition

Teconin™ 200: Each vial contains Teicoplanin BP 200 mg Lyophilized Powder for IM/IV Injection

Teconin™ 400: Each vial contains Teicoplanin BP 400 mg Lyophilized Powder for IM/IV Injection

Pharmacology

Teicoplanin is a Glycopeptide-antibiotic produced by *Actinoplanes teichomyceticus*. Teicoplanin inhibits the growth of susceptible organisms by interfering with cell-wall biosynthesis at a site different from that affected by beta-lactams. Peptidoglycan synthesis is blocked by specific binding to D-alanyl-D-alanine residues.

Indications & uses

Teconin™ is indicated in adults and in children of the following infections-

- Complicated skin and soft tissue infections
- Bone and joint infections
- Hospital acquired pneumonia
- Community acquired pneumonia
- Complicated urinary tract infections
- Infective endocarditis

Teconin™ is also indicated as an alternative oral treatment for *Clostridium difficile* infection-associated diarrhoea and colitis. Where appropriate, Teicoplanin should be administered in combination with other antibacterial agents.

Dosage & Administration

Method of reconstitution:

Add slowly 3 ml of water for injection from the ampoule into the **Teconin™ 200** and **Teconin™ 400** vial. While adding water for injection to the vial rotate the vial gently until all the powder is dissolved to avoid foaming. If foam is developed, allow the solution to stand for approximately 15 minutes so that the foam disappears. The color of the solution may vary from yellowish to dark yellow. Teicoplanin can be administered in the following infusion solutions:

- 0.9% Sodium chloride solution
- Ringer solution
- Ringer-lactate solution
- 5% dextrose solution
- 10% dextrose solution
- 0.18% sodium chloride and 4% glucose solution
- 0.45% sodium chloride and 5% glucose solution

Teconin™ can be given intravenously (as a bolus injection or infusion) or intramuscularly. The intravenous injection may be administered either as a bolus over 3 to 5 minutes or as a 30-minute infusion. Only the infusion method should be used in neonates. It should be given once daily after one or more loading doses. The dosage of **Teconin™** should be adapted on the severity of the infection and patient's response to treatment.

In adults (Normal kidney function) - On the first day, a dose of 6 mg/kg (generally 400 mg) intravenously is recommended. On the following days, the dose may be 6 mg/kg/day (generally 400 mg) intravenously or 3 mg/kg/day (generally 200 mg) intravenously or intramuscularly as a single daily dose. The highest dose and the intravenous route are recommended for serious infections.

- In potentially fatal infections, treatment should be started with 6 mg/kg (usually 400 mg) twice daily for 1 to 4 days (loading dose) and continued with 6 mg/kg/day intravenously on the following days (maintenance dose).

In adults and elderly (Kidney failure)

In patients with kidney failure, the dosage should be adjusted from the 4th day of treatment as follows:

- In moderate kidney failure (creatinine clearance between 40 and 60

ml/min), the daily dose of **Teconin™** should be halved or given on alternate days.

- In severe kidney failure (creatinine clearance less than 40 ml/min) and in hemodialysis patients, the daily dose of **Teconin™** should be reduced to a third, or given every 3 days.

- If creatinine clearance is equal to or less than 20 ml/min, treatment with **Teconin™** may be given only if monitoring of drug levels in the blood can be guaranteed.

In children (Normal kidney function)

In Children (2 months to 12 years): Treatment should be started at a dose of 10 mg/kg every 12 hours for a total of 3 doses and then continued at a dose of 6-10 mg/kg/day, the highest dose being used for the most serious infections or for children with neutropenia.

In neonates (up to 2 months): Treatment should be started at a dose of 16 mg/kg on the first day, followed by maintenance doses of 8 mg/kg/day by slow intravenous infusion (lasting approximately 30 minutes).

In children (Kidney failure)

As like adults, dosage adjustment is recommended. Measuring **Teconin™** levels in the blood may be useful to make treatment as effective as possible.

Clostridium difficile infection associated diarrhea

The recommended dose is 100-200 mg administered twice a day for 7 to 14 days.

Giving **Teconin™** along with another suitable bactericidal antibiotic is recommended for infections requiring maximum bactericidal activity or in situations where the presence of Gram-negative bacteria cannot be ruled out (empirical treatment of fever in patients with neutropenia). In most patients, this medicine can be seen to have an effect 48 to 72 hours after the start of treatment. However, the total duration of treatment is determined based on the type and severity of the infection and the patient's response to treatment. In endocarditis and osteomyelitis, a period of at least 3 weeks is recommended.

Contraindication

Teicoplanin is contraindicated in patients with known hypersensitivity to the drug.

Precaution

Teicoplanin should be administered with caution in patients known to be hypersensitive to Vancomycin since cross-hypersensitivity may occur.

Adverse effects

Local reaction: Erythema, injection site abscess when given intramuscularly.

Allergic reaction: Rash, pruritus, fever, shivering, anaphylactic reactions. **Gastrointestinal reactions:** Nausea, vomiting, diarrhea. **CNS reactions:** Physical weakness, dizziness, headache. **Hearing reactions:** Ringing in the ears, balance disorders.

Use in Pregnancy and Lactation

Pregnancy

Pregnancy Category B3. Teicoplanin should not be used during confirmed or presumed pregnancy unless the potential benefits outweigh possible risks.

Lactation

Teicoplanin should not be used during lactation unless the potential benefits outweigh possible risks.

Drug interaction

Due to potential for increased adverse effects, **Teconin™** should be administered with caution in patients receiving concurrent nephrotoxic or ototoxic drugs, such as Aminoglycosides, Amphotericin B, Cyclosporin and Frusemide.

Storage

Store at temperature not exceeding 30°C in a dry place. Protect from light. Reconstituted solution should be used immediately, or should be stored under refrigeration (2° to 8° C) for maximum 24 hours.

How supplied

Teconin™ 200mg IM/IV Injection: Each box contains one filled vial of Lyophilized Powder equivalent to 200mg Teicoplanin BP, one ampoule of 5 ml Water for Injection and one 3ml disposable syringe.

Teconin™ 400mg IM/IV Injection: Each box contains one filled vial of Lyophilized Powder equivalent to 400mg Teicoplanin BP, one ampoule of 5 ml Water for Injection and one 3ml disposable syringe.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH