Teicoplanin – Dosing

Recommendation for the harmonisation of SPCs regarding dosing (EC decision September 2013)

The dose and duration of treatment should be adjusted according to the underlying type and severity of infection and clinical response of the patient, and patient factors such as age and renal function.

Measurement of serum concentrations:

Teicoplanin trough serum concentrations should be monitored at steady state after completion of the loading dose regimen in order to ensure that a minimum trough serum concentration has been reached:

- For most Gram-positive infections, teicoplanin trough levels of at least 10 mg/L when measured by High Performance Liquid Chromatography (HPLC), or at least 15 mg/L when measured by Fluorescence Polarization Immunoassay (FPIA) method.
- For endocarditis and other severe infections, teicoplanin trough levels of 15-30 mg/L when measured by HPLC, or 30-40 mg/L when measured by FPIA method.

During maintenance treatment, teicoplanin trough serumconcentrations monitoring may be performed at least once a week to ensure that these concentrations are stable.

Adults and elderly patients with normal renal function:

Indications	Loading dose		Maintenance dose	
	Loading dose regimen	Targeted trough concentrations at day 3 to 5*	Maintenance dose	Targeted trough concentrations during maintenance*
- Complicated skin and soft tissue infections - Pneumonia - Complicated urinary tract infections	400 mg intravenous or intramuscular (approximately 6 mg/kg body weight) every 12 hours for 3 administrations	>15 mg/L	6 mg/kg body weight intravenous or intramuscular once a day	>15 mg/L once a week
- Bone and joint infections	800 mg intravenous (approximately 12 mg/kg body weight) every 12 hours for 3 to 5 administrations	>20 mg/L	12 mg/kg body weight intravenous or intramuscular once a day	>20 mg/L
- Infective endocarditis	800 mg intravenous (approximately 12 mg/kg body weight) every 12 hours for 3 to 5	30-40 mg/L	12 mg/kg body weight intravenous or intramuscular once a day	>30 mg/L

	administrations			

*Measured by FPIA

Duration of treatment

The duration of treatment should be decided based on the clinical response. For infective endocarditis a minimum of 21 days is usually considered appropriate. Treatment should not exceed 4 months.

Combination therapy

Teicoplanin has a limited spectrum of antibacterial activity (Gram positive). It is not suitable for use as a single agent for the treatment of some types of infections unless the pathogen is already documented and known to be susceptible or there is a high suspicion that the most likely pathogen(s) would be suitable for treatment with teicoplanin.

Clostridium difficile infection-associated diarrhea and colitis

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

Elderly population

No dose adjustment is required, unless there is renal impairment (see below).

Post-authorisation safety study (PASS)

The MAH shall conduct a non-interventional study to evaluate the safety of Targocid in adults with Gram-positive infections who are exposed to the higher loading dose of 12mg/kg twice a day (24 mg/kg/day). The MAH shall submit a RMP within 6 months of the Commission Decision.

Adults and elderly patients with impaired renal function

Dose adjustment is not required until the fourth day of treatment, at which time dosing should be adjusted to maintain a serum trough concentration of at least 10 mg/L.

After the fourth day of treatment:

- In mild and moderate renal insufficiency (creatinine clearance 30-80 mL/min): maintenance dose should be halved, either by administering the dose every two days or by administering half of this dose once a day.
- In severe renal insufficiency (creatinine clearance less than 30 mL/min) and in haemodialysed patients: dose should be one-third the usual dose, either by administering the initial unit dose every third day or by administering one-third of this dose once a day.

Teicoplanin is not removed by haemodialysis.

Patients in continuous ambulatory peritoneal dialysis (CAPD)

After a single intravenous loading dose of 6 mg/kg bodyweight, 20 mg/L is administered in the bag of the dialysis solution in the first week, 20 mg/L in different bags the second week and then 20 mg/L in the overnight bag in the third week.

Paediatric population

The dose recommendations are the same in adults and children above 12 years of age.

<u>Neonates and infants up to the age of 2 months</u>:

Loading dose: One single dose of 16 mg/kg body weight, administered intravenously by infusion on the first day.

Maintenance dose: One single dose of 8 mg/kg body weight administered intravenously by infusion once a day.

Children (2 months to 12 years):

Loading dose: One single dose of 10 mg/kg body weight administered intravenously every 12 hours, repeated 3 times.

Maintenance dose: One single dose of 6-10 mg/kg body weight administered intravenously once a day.

Method of administration

Teicoplanin should be administered by the intravenous or intramuscular route. 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.