MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS

INSTRUCTION
for Medical Use of Medicinal Product

TEICOPLANIN-TF
powder for solution for intravenous and intramuscular administration 200 mg, 400 mg

Stamp: [APPROVED
by the MINISTRY OF HEALTH
OF THE REPUBLIC OF BELARUS
Order of the Ministry of Health
of the Republic of Belarus
No. 1089 dd. 14.10.2020
MC No. 7 dd. 29.09.2020]

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions according to the appropriate form.

Trade name Teicoplanin-TF.
International non-proprietary name Teicoplanin.
Pharmaceutical form Powder for solution for intravenous and intramuscular administration 200 mg, 400 mg.
Description Amorphous powder of yellowish color.
Composition per 1 vial
Teicoplanin – 200 mg equivalent to not less than 200 000 IU.
Teicoplanin – 400 mg equivalent to not less than 400 000 IU.
After reconstitution, 3 ml of solution contains 200 mg or 400 mg of Teicoplanin respectively.
Pharmacotherapeutic group Antibacterials for systemic use. Other antibacterial agents. Glycopeptide antibacterials.
ATC code J01XA02.
Pharmacological properties
Pharmacodynamics
Teicoplanin is a complex glycopeptide which inhibits the growth of susceptible microorganisms 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.
Resistance to teicoplanin can be based on the following mechanisms: modified target structure and overproduction of murein precursors. Modified target structure has occurred particularly in *Enterococcus faecium*. The modification is based on exchange of the terminal D-alanine-D-alanine function of the amino-acid chain in a murein precursor with D-Ala-D-lactate, thus reducing the affinity to teicoplanin. The responsible enzymes are a newly synthesised D-lactate dehydrogenase or ligase. The reduced sensitivity or resistance of staphylococci to teicoplanin is based on the overproduction of murein precursors to which teicoplanin is bound.
Cross-resistance between teicoplanin and the glycoprotein vancomycin may occur. A number of vancomycin-resistant enterococci are sensitive to teicoplanin (Van-B phenotype).
Breakpoints
The European Committee on Antimicrobial Susceptibility Testing (EUCAST, v. 7.1, 2017) established minimal inhibiting concentrations (MICs) breakpoints of teicoplanin to identify susceptible and resistant pathogens.

Minimum inhibitory concentrations (MICs) breakpoints

Microorganism	**Susceptible**	**Resistant**
Staphylococcus aureus [a, b]	≤2 mg/L	>2 mg/L
Coagulase-negative staphylococci [a, b]	≤4 mg/L	>4 mg/L
Enterococcus spp.	≤2 mg/L	>2 mg/L
Streptococcus groups A, B, C, G [b]	≤2 mg/L	>2 mg/L
Streptococcus pneumoniae [b]	≤2 mg/L	>2 mg/L
Viridans group streptococci [b]	≤2 mg/L	>2 mg/L
Gram-positive anaerobes except *Clostridium difficile*	IE	IE
PK/PD (Non-species related) breakpoints	IE	IE

[a] Glycopeptide MICs are method dependent and should be determined by broth microdilution (according to ISO 20776). *S. aureus* with vancomycin MIC values of 2 mg/L are on the border of the wild type MIC distribution and there may be an impaired clinical response. The resistance breakpoint for *S. aureus* has been reduced to 2 mg/L to avoid reporting of GISA isolates intermediate as serious infections with GISA isolates are not treatable with increased doses of vancomycin or teicoplanin (GISA - glycopeptide-intermediate S. aureus).
[b] Non-susceptible isolates are rare or not yet reported. The identification and antimicrobial susceptibility test result on any such isolate must be confirmed and the isolate sent to a reference laboratory.
"IE" indicates that there is insufficient evidence that the organism or group is a good target for therapy with the agent. A MIC with a comment but without an accompanying Susceptible, Intermediate or Resistant categorisation may be reported.

Pharmacokinetic/Pharmacodynamic relationship

Teicoplanin antimicrobial activity depends essentially on the duration of time during which the medicinal product level is higher than the MIC of the pathogen.

Susceptibility

The prevalence of resistance may vary geographically and over time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some of types of infections is questionable.

Teicoplanin is active against the following microorganisms:

Gram-positive aerobes: *Corynebacterium jeikeium*[a], *Enterococcus faecalis*, *Staphylococcus aureus* (including methicillin-resistant strains), *Streptococcus agalactiae*, *Streptococcus dysgalactiae* subsp. *equisimilis*[a], (Group C, G streptococci), *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococci* in the viridans group[a,b].

Gram-positive anaerobes: *Clostridium difficile*[a], *Peptostreptococcus* spp.[a]

Species for which acquired resistance may be a problem:

Gram-positive aerobes: *Enterococcus faecium*, *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Staphylococcus hominis*.

Inherently resistant bacteria: *Chlamydia* spp., *Chlamydophila* spp., *Legionella pneumophila*, *Mycoplasma* spp., all Gram-negative bacteria.

Pharmacokinetics

Absorption

After intramuscular administration, the bioavailability of teicoplanin (as compared to intravenous administration) is almost complete (90%). After six daily intramuscular administrations of 200 mg the mean (SD) maximum teicoplanin concentration (C_{max}) amounts to 12.1 (0.9) mg/L and occurs at 2 hours after administration.

[a] No current data were available when the tables were published. The primary literature, standard volumes and treatment recommendations assume sensitivity.
[b] Collective term for a heterogeneous group of streptococcus species. Resistance rate can vary depending on the actual streptococcus species.

After a loading dose of 6 mg/kg administered intravenously every 12 hours for 3 to 5 administrations, C_{max} values range from 60 to 70 mg/L and C_{trough} are usually above 10 mg/L. After an intravenous loading dose of 12 mg/kg administered every 12 hours for 3 administrations, mean values of C_{max} and C_{trough} are estimated to be around 100 mg/L and 20 mg/L, respectively.
After a maintenance dose of 6 mg/kg administered once daily C_{max} and C_{trough} values are approximately 70 mg/L and 15 mg/L, respectively. After a maintenance dose of 12 mg/kg once daily C_{trough} values range from 18 to 30 mg/L.
When administered by oral route teicoplanin is not absorbed from the gastrointestinal tract. When administered by oral route at 250 or 500 mg single dose to healthy subjects, teicoplanin is not detected in serum or urine but only recovered in feces (about 45% of the administered dose) as unchanged medicinal product.
Distribution
The binding to human serum proteins ranges from 87.6 to 90.8% without any variation in function of the teicoplanin concentrations. Teicoplanin is mainly bound to human serum albumin. Teicoplanin is not distributed in red cells.
The volume of distribution at steady-state (Vss) varies from 0.7 to 1.4 L/kg. The highest values of Vss are observed in the recent studies where the sampling period was superior to 8 days.
Teicoplanin distributed mainly in lung, myocardium and bone tissues with tissue/serum ratios superior to 1. In blister fluids, synovial fluid and peritoneal fluid the tissue/serum ratios ranged from 0.5 to 1. Elimination of teicoplanin from peritoneal fluid occurs at the same rate as from serum. In pleural fluid and subcutaneous fat tissue the tissue/serum ratios are comprised between 0.2 and 0.5. Teicoplanin does not readily penetrate into the cerebrospinal fluid (CSF).
Biotransformation and Elimination
Unchanged form of teicoplanin is the main compound identified in plasma and urine, indicating minimal metabolism. Two metabolites are formed probably by hydroxylation and represents 2 to 3% of the administered dose.
Unchanged teicoplanin is mainly excreted by urinary route (80% within 16 days) while 2.7% of the administered dose is recovered in feces (via bile excretion) within 8 days following administration. Elimination half-life of teicoplanin varies from 100 to 170 hours in the most recent studies where blood sampling duration is about 8 to 35 days.
Teicoplanin has a low total clearance in the range of 10 to 14 mL/h/kg and a renal clearance in the range of 8 to 12 mL/h/kg indicating that teicoplanin is mainly excreted by renal mechanisms.
Linearity
Teicoplanin exhibited linear pharmacokinetics at dose range of 2 to 25 mg/kg.
Pharmacokinetics in special populations
As teicoplanin is eliminated by renal route, teicoplanin elimination decreases according to the degree of *renal impairment*. The total and renal clearances of teicoplanin depends on the creatinine clearance.
In the *elderly population* the teicoplanin pharmacokinetics is not modified unless in case of renal impairment.
Paediatric population
A higher total clearance (15.8 mL/h/kg for neonates, 14.8 mL/h/kg for a mean age 8 years) and a shorter elimination half-life (40 hours for neonates; 58 hours for 8 years) are observed compared to adult patients.

Preclinical safety data

Following repeated parenteral administration to the rat and dog, dose-dependent and reversible effects on the kidney were observed. Studies to investigate the potential to cause ototoxicity in the guinea-pig indicate that a mild impairment of cochlear and vestibular function is possible, in the absence of morphological damage.
Subcutaneous administration of teicoplanin at up to 40 mg/kg/day did not affect male and female fertility in the rat. In embryofetal development studies, no malformations were observed following subcutaneous administration of up to 200 mg/kg/day in the rat and intramuscular

administration up to 15 mg/kg/day in the rabbit. However, in the rat, there was an increased incidence of stillbirths at doses of 100 mg/kg/day and above and neonatal mortality at 200 mg/kg/day. This effect was not reported at 50 mg/kg/day. A peri- and postnatal study in rats showed no effects on the fertility of the F1 generation or on the survival and development of the F2 generation following subcutaneous administration of up to 40 mg/kg/day.
Teicoplanin did not show any potential to cause antigenicity (in mice, guinea-pigs or rabbits), genotoxicity or local irritancy.

Therapeutic indications

Teicoplanin-TF is indicated in adults and in children from birth for the parenteral treatment 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,
- peritonitis associated with continuous ambulatory peritoneal dialysis (CAPD),
- bacteraemia that occurs in association with any of the indications listed above.

Teicoplanin-TF 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.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Contraindications

Hypersensitivity to teicoplanin.

Special warnings and precautions for use

Use during pregnancy and breastfeeding
There are limited data from the use of teicoplanin in pregnant women. Studies in animals have shown reproductive toxicity at high doses: in rats there was an increased incidence of stillbirths and neonatal mortality. The potential risk for humans is unknown.
Therefore, Teicoplanin-TF should not be used during pregnancy unless clearly necessary. A potential risk of inner ear and renal damage to the foetus cannot be excluded.
It is unknown whether teicoplanin is excreted in human milk. There is no information on the excretion of teicoplanin in animal milk. A decision on whether to continue/discontinue *breast-feeding* or to continue/discontinue therapy with teicoplanin should be made taking into account the benefit of breast-feeding to the child and the benefit of teicoplanin therapy to the mother.
Animal reproduction studies have not shown evidence of impairment of *fertility*.
Effects on ability to drive and use machines
Teicoplanin can cause dizziness and headache. The ability to drive or use machines may be affected. Patients experiencing these undesirable effects should not drive or use machines.
Special warnings
Serious, life-threatening *hypersensitivity reactions*, sometimes fatal, have been reported with teicoplanin (e.g. *anaphylactic shock*). If an allergic reaction to teicoplanin occurs, treatment should be discontinued immediately and appropriate emergency measures should be initiated.
Teicoplanin-TF must be administered *with caution* in patients with known hypersensitivity to vancomycin, as crossed hypersensitivity reactions, including fatal *anaphylactic shock*, may occur. However, a prior history of "red man syndrome" with vancomycin is not a contraindication to the use of teicoplanin.
Infusion related reactions
In rare cases (even at the first dose), “red man syndrome” (a complex of symptoms including pruritus, urticaria, erythema, angioneurotic oedema, tachycardia, hypotension, dyspnoea) has been observed. Stopping or slowing the infusion may result in cessation of these reactions.

Infusion related reactions can be limited if the daily dose is not given via bolus injection but infused over a 30-minute period.

Severe bullous reactions

Life-threatening or even fatal cutaneous reactions Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) have been reported with the use of teicoplanin. If symptoms or signs of SJS or TEN (e.g. progressive skin rash often with blisters or mucosal lesions) are present *treatment with Teicoplanin-TF should be discontinued immediately!*

Spectrum of antibacterial activity

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.

The rational use of Teicoplanin-TF should take into account the bacterial spectrum of activity, the safety profile and the suitability of standard antibacterial therapy to treat the individual patient. On this basis it is expected that in most instances Teicoplanin-TF will be used to treat severe infections in patients for whom standard antibacterial activity is considered to be unsuitable.

Loading dose regimen

Since data on safety are limited, patients should be carefully monitored for adverse reactions when teicoplanin doses of 12 mg/kg body weight twice a day are administered. Under this regimen blood creatinine values should be monitored in addition to the recommended periodic haematological examination.

Teicoplanin should not be administered by intraventricular use!

Thrombocytopenia has been reported with teicoplanin. Periodic haematological examinations are recommended during treatment, including complete cell blood count.

Renal failure has been reported in patients treated with teicoplanin. Patients with renal insufficiency, and/or in those receiving teicoplanin in conjunction with or sequentially with other medicinal products with known nephrotoxic potential (aminoglycosides, colistin, amphotericin B, ciclosporin, and cisplatin) should be carefully monitored, and should include auditory tests.

Since teicoplanin is mainly excreted by the kidney, the dose of Teicoplanin-TF must be adapted in patients with renal impairment.

As with other glycopeptides, *ototoxicity* (deafness and tinnitus) has been reported in patients treated with teicoplanin. Patients who develop signs and symptoms of impaired hearing or disorders of the inner ear during treatment with Teicoplanin-TF should be carefully evaluated and monitored, especially in case of prolonged treatment and in patients with renal insufficiency. Patients receiving teicoplanin in conjunction with or sequentially with other medicinal products with known neurotoxic/ototoxic potential (aminoglycosides, ciclosporin, cisplatin, furosemide and ethacrynic acid) should be carefully monitored and the benefit of teicoplanin evaluated if hearing deteriorates. Special precautions must be taken when administering teicoplanin in patients who require concomitant treatment with ototoxic and/or nephrotoxic medicinal products for which it is recommended that regular haematology, liver and kidney function tests are carried out.

As with other antibiotics, the use of teicoplanin, especially if prolonged, may result in *overgrowth of non-susceptible organisms*. If superinfection occurs during therapy, appropriate measures should be taken.

Posology and method of administration

The dose and duration of treatment with Teicoplanin-TF 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 serum concentrations 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	6 mg/kg body weight every 12 hours for 3 intravenous or intramuscular administrations	> 15 mg/L[1]	6 mg/kg body weight intravenous or intramuscular once a day	> 15 mg/L[1] once a week
- Bone and joint infections	12 mg/kg body weight every 12 hours for 3 to 5 intravenous administrations	> 20 mg/L[1]	12 mg/kg body weight intravenous or intramuscular once a day	> 20 mg/L[1]
- Infective endocarditis	12 mg/kg body weight every 12 hours for 3 to 5 intravenous administrations	30-40 mg/L[1]	12 mg/kg body weight intravenous or intramuscular once a day	> 30 mg/L[1]

[1] Measured by FPIA.

The dose is to be adjusted on bodyweight whatever the weight of the patient.

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). Teicoplanin-TF 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.

In case of *Clostridium difficile infection-associated diarrhoea and colitis*, Teicoplanin-TF is administered in the dose of 100-200 mg administered orally twice a day for 7 to 14 days.

No dose adjustment is required in *elderly*, unless there is renal impairment.

Dose adjustment is not required in *adults and elderly patients with impaired renal function* 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 when measured by HPLC, or at least 15 mg/L when measured by FPIA method.
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.
For patients on 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.
The loading dose for *neonates and infants up to the age of 2 months* – one single dose of 16 mg/kg body weight, administered intravenously by infusion on the first day. The maintenance dose is 8 mg/kg body weight administered intravenously by infusion once a day.
Children (2 months to 12 years): loading dose is 10 mg/kg body weight administered intravenously every 12 hours, repeated 3 times; maintenance dose is 6-10 mg/kg body weight administered intravenously once a day.
Method of administration
Teicoplanin-TF 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*.
For *Clostridium difficile infection-associated diarrhoea and colitis*, the oral route is to be used.
Preparation and administration of solutions
The solution is reconstituted by adding 3 ml of water for injection to 200 mg or 400 mg powder vial. The solvent should be injected slowly into the vial, shaking gently the vial until the powder is completely dissolved, avoiding the appearance of foam. In case of foaming, leave the vial with solution in an upright position for approximately 15 minutes to reduce its amount. Only clear, yellowish to brownish solutions should be used. Chemical and physical in-use stability of the reconstituted solution prepared as recommended has been demonstrated for 24 hours at 2 to 8°C (refrigerator). From a microbiological point of view, the medicinal product should be used immediately, otherwise the in-use storage times and conditions are the responsibility of user.
The reconstituted solution may be used for injection or may be diluted with one of the following solvents: 0.9% sodium chloride solution, Ringer solution, Ringer-lactate solution, 5% dextrose injection, 10% dextrose injection, 0.18% sodium chloride and 4% glucose solution, 0.45% sodium chloride and 5% glucose solution, peritoneal dialysis solution containing 1.36% or 3.86% of glucose.
To prevent the injection of the fewer doses than required, the medicinal product should be completely dissolved. The prepared solution should be carefully removed from the vial!
At dilution of Teicoplanin-TF standard aseptic techniques should be met.
Chemical and physical in-use stability of the diluted solutions has been demonstrated for 24 hours at 2 °C to 8 °C. From a microbiological point of view, the medicinal product should be used immediately, otherwise the in-use storage times and conditions are the responsibility of user.
If teicoplanin is administered in combination therapy with other antibiotics, the preparation must be administered separately.
This medicinal product must not be mixed with other medicinal products except those mentioned in this section.

Undesirable effects

Adverse drug reactions are listed below by frequency categories. Frequency categories are defined as follows: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); unknown (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Adverse reactions should be monitored when teicoplanin doses of 12 mg/kg body weight twice a day are administered.

Infections and infestations: rare - abscess; unknown - superinfection (increasing of the number of non-susceptible organisms).

Blood and lymphatic system disorders: uncommon - leukopenia, thrombocytopenia, eosinophilia; unknown - agranulocytosis, neutropenia.

Immune system disorders: uncommon - anaphylactic reaction (anaphylaxis); unknown - drug reaction with eosinophilia and systemic symptoms (DRESS), anaphylactic shock.

Nervous system disorders: uncommon - dizziness, headache; unknown - seizures.

Ear and labyrinth disorders: uncommon - deafness, hearing loss, tinnitus, vestibular disorder.

Vascular disorders: common - phlebitis; unknown - thrombophlebitis.

Respiratory, thoracic and mediastinal disorders: uncommon - bronchospasm.

Gastrointestinal disorders: uncommon - diarrhea, vomiting, nausea.

Skin and subcutaneous tissue disorders: common - rash, erythema, pruritus; rare – "red man syndrome" (e.g. flushing of the upper part of the body); unknown - toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, angioedema, dermatitis exfoliative, urticaria.

Renal and urinary disorders: uncommon - blood creatinine increase; unknown - renal failure (including acute renal failure).

General disorders and administration site conditions: common - pain, pyrexia; unknown - injection site abscess, chills (rigors).

Investigations: uncommon - transaminase increased (transient abnormality of transaminases), blood alkaline phosphatase increased (transient abnormality of alkaline phosphatase), blood creatinine increased (transient rise of serum creatinine).

Reporting of adverse reactions

It is important to report suspected adverse reactions after drug product registration in order to ensure continuous monitoring of the benefit-to-risk ratio. Healthcare providers are encouraged to report any suspected adverse drug reactions through national ADR systems.

If any adverse reactions occur, patients are advised to consult a doctor or report adverse reactions to the Adverse Drug Reactions Information Database.

This recommendation applies to any possible adverse reactions, including those not listed in the instructions for medical use, including reports of ineffectiveness of the drug product. Adverse reaction reports provide more information on the safety of a drug product.

Overdosing

Symptoms

Cases of accidental administration of excessive doses to paediatric patients have been reported. In one case agitation occurred in a 29-day-old newborn who had been administered 400 mg of teicoplanin intravenously (95 mg/kg).

Management

Treatment of teicoplanin overdose should be symptomatic. Teicoplanin-TF is not excreted from the body by hemodialysis.

Interaction with other medicinal products and other forms of interaction

No specific interaction studies have been performed.

The simultaneous injection of Teicoplanin-TF and aminoglycosides is not allowed. Their concomitant use is possible in the dialysis solution for the treatment of peritonitis associated with continuous ambulatory peritoneal dialysis. Teicoplanin-TF *should be used with care* in conjunction with or sequentially with other medicinal products with known nephrotoxic or ototoxic potential (aminoglycosides, colistin, amphotericin B, ciclosporin, cisplatin, furosemide,

and ethacrynic acid). However, there is no evidence of synergistic toxicity in combinations with teicoplanin.
In clinical studies teicoplanin has been administered to many patients already receiving various medications including other antibiotics, antihypertensives, anaesthetic agents, cardiac medicinal products and antidiabetic agents without evidence of adverse interaction.
Paediatric population
Interaction studies have only been performed in adults.

Storage and shelf life

Keep protected from light at a temperature from 2 ^{o}C to 8 ^{o}C.
Keep out of the reach of children.
Shelf life is 2 years. Do not use beyond the expiration date printed on the package.

Prescription status

Prescription only medicinal product.

Packaging

200 mg or 400 mg in 10 ml vials for injection of the III hydrolytic class made of cast colorless glass. Vials are corked with rubber stoppers and plugged up by aluminum caps with plastic covers with inscription "FLIP OFF" or without inscription. Self-adhesive labels are attached on vials.
5 vials with the instruction for medical use are placed in a cardboard pack.
36 vials with the instructions for medical use are placed in a cardboard box (package for hospitals).

Information about manufacturer

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