Annex III

Summary of product characteristics, labelling and package leaflet

Note:

This SmPC, labelling and packages leaflet is the version valid at the time of Commission decision.

After the Commission decision the Member State competent authorities, in liaison with the reference Member State, will update the product information as required. Therefore, this SmPC, labelling and package leaflet may not necessarily represent the current text.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Targocid and associated names (see Annex I) 100 mg powder and solvent for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 200 mg powder and solvent for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 400 mg powder and solvent for solution for injection/infusion or oral solution

Targocid and associated names (see Annex I) 100 mg powder for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 200 mg powder for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 400 mg powder for solution for injection/infusion or oral solution

[See Annex I - To be completed nationally]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 100 mg teicoplanin equivalent to not less than 100,000 IU
After reconstitution, the solutions will contain 100 mg teicoplanin in 1.5 mL

Each vial contains 200 mg teicoplanin equivalent to not less than 200,000 IU
After reconstitution, the solutions will contain 200 mg teicoplanin in 3.0 mL

Each vial contains 400 mg teicoplanin equivalent to not less than 400,000 IU.
After reconstitution, the solutions will contain 400 mg teicoplanin in 3.0 mL.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection/infusion or oral solution
Powder for solution for injection/infusion or oral solution

Powder for solution for injection/infusion or oral solution: spongy ivory coloured homogeneous mass
Solvent: clear, colourless liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Targocid and associated names (see Annex I) is indicated in adults and in children from birth for the parenteral treatment of the following infections (see sections 4.2, 4.4 and 5.1):

- 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.

Targocid and associated names (see Annex I) 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.

4.2 Posology and method of administration

Posology
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 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	400 mg intravenous or intramuscular (this equates to approximately 6 mg/kg body weight) every 12 hours for 3 administrations	>15 mg/L[1]	6 mg/kg body weight intravenous or intramuscular once a day	>15 mg/L[1] once a week

Indications	Loading dose		Maintenance dose	
	Loading dose regimen	**Targeted trough concentrations at day 3 to 5**	**Maintenance dose**	**Targeted trough concentrations during maintenance**
- Bone and joint infections	800 mg intravenous (this equates to approximately 12 mg/kg body weight) every 12 hours for 3 to 5 administrations	>20 mg/L[1]	12 mg/kg body weight intravenous or intramuscular once a day	>20 mg/L[1]
- Infective endocarditis	800 mg intravenous (this equates to approximately 12 mg/kg body weight) every 12 hours for 3 to 5 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

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).

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.

Neonates and infants up to the age of 2 months:
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.

For instructions on reconstitution and dilution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to teicoplanin or to any of the excipients listed in section 6.

4.4 Special warnings and precautions for use

Hypersensitivity reactions
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 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 teicoplanin treatment 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 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 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 12mg/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
Thrombocytopenia has been reported with teicoplanin. Periodic haematological examinations are recommended during treatment, including complete cell blood count.

Nephrotoxicity
Renal failure has been reported in patients treated with teicoplanin (see section 4.8). 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 must be adapted in patients with renal impairment (see section 4.2).

Ototoxicity
As with other glycopeptides, ototoxicity (deafness and tinnitus) has been reported in patients treated with teicoplanin (see section 4.8). Patients who develop signs and symptoms of impaired hearing or disorders of the inner ear during treatment with teicoplanin 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.

Superinfection
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.

4.5 Interaction with other medicinal products and other forms of interaction

No specific interaction studies have been performed.

Teicoplanin and aminoglycoside solutions are incompatible and must not be mixed for injection; however, they are compatible in dialysis fluid and may be freely used in the treatment of CAPD-related peritonitis. Teicoplanin should be used with care in conjunction with or sequentially with other medicinal products with known nephrotoxic or ototoxic potential. These include aminoglycosides, colistin, amphotericin B, ciclosporin, cisplatin, furosemide, and ethacrynic acid (see section 4.4). 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.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are a limited amount of data from the use of teicoplanin in pregnant women. Studies in animals have shown reproductive toxicity at high doses (see section 5.3): in rats there was an increased incidence of stillbirths and neonatal mortality. The potential risk for humans is unknown.
Therefore, teicoplanin should not be used during pregnancy unless clearly necessary. A potential risk of inner ear and renal damage to the foetus cannot be excluded (see section 4.4).

Breast-feeding
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.

Fertility
Animal reproduction studies have not shown evidence of impairment of fertility.

4.7 Effects on ability to drive and use machines

Targocid and associated names (see Annex I) has minor influence on the 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.

4.8 Undesirable effects

Tabulated list of adverse reactions
In the table below all the adverse reactions, which occurred at an incidence greater than placebo and more than one patient are listed using the following convention:
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); not known (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 (see section 4.4).

System organ class	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)	Not known (cannot be estimated from available data)
Infections and infestations			Abcess		Superinfection (overgrowth of non-susceptible organisms)
Blood and the lymphatic system disorders		Leucopenia, thrombocytopenia, eosinophilia			Agranulocytosis, neutropenia
Immune system disorders		Anaphylactic reaction (anaphylaxis) (see section 4.4)			Anaphylactic shock (see section 4.4)
Nervous system disorders		Dizziness, headache			Seizures
Ear and Labyrinth disorders		Deafness, hearing loss (see section 4.4), tinnitus, vestibular disorder			
Vascular disorders		Phlebitis			Thrombophlebitis
Respiratory, thoracic and mediastinal disorders		Bronchospasm			
Gastro-intestinal disorders		Diarrhoea, vomiting, nausea			
Skin and subcutaneous tissue disorders	Rash, erythema, pruritus		Red man syndrome (e.g. Flushing of the upper part of the body) (see section 4.4).		Toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, angioedema, dermatitis exfoliative, urticaria (see section 4.4)
Renal and Urinary disorders		Blood creatinine increased			Renal failure (including renal failure acute)
General disorders and administration site conditions	Pain, pyrexia				Injection site abcess, chills (rigors)

System organ class	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)	Not known (cannot be estimated from available data)
Investigations		Transaminases increased (transient abnormality of transaminases), blood alkaline phosphatase increased (transient abnormality of alkaline phosphatase), blood creatinine increased (transient rise of serum creatinine)			

4.9 Overdose

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 intravenously (95 mg/kg).

Management
Treatment of teicoplanin overdose should be symptomatic.
Teicoplanin is not removed by haemodialysis and only slowly by peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Glycopeptide Antibacterials, ATC code: J01XA 02

Mechanism of action
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.

Mechanism of resistance
Resistance to teicoplanin can be based on the following mechanisms:

- Modified target structure: this form of resistance 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 vancomycin. 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).

Susceptibility testing breakpoints

The MICs breakpoints according to the European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 3.1, February 11, 2013 are displayed in the following table:

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

a Glycopeptide MICs are method dependent and should be determined by broth microdilution (reference ISO 20776). *S. aureus* with vancomycin MIC values of 2 mg/mL 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/mL to avoid reporting of GISA isolates intermediate as serious infections with GISA isolates are not treatable with increased doses of vancomycin or teicoplanin.

b Isolates with MIC values above the susceptible breakpoint are very rare or not yet reported. The identification and antimicrobial susceptibility tests on any such isolate must be repeated and if the result is confirmed the isolate must be sent to a reference laboratory. Until there is evidence regarding clinical response for confirmed isolates with MIC above the current resistant breakpoint they should be reported resistant.

c IE indicates that there is insufficient evidence that the species in question is a good target for therapy with the drug.

d A MIC with a comment but without an accompanying S, I or R categorisation may be reported.

Pharmacokinetic/Pharmacodynamic relationship

Teicoplanin antimicrobial activity depends essentially on the duration of time during which the substance level is higher than the minimum inhibitory concentration (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.

Commonly susceptible species
Aerobic Gram-positive bacteria
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]
Anaerobic Gram-positive bacteria
Clostridium difficile [a]
Peptostreptococcus spp.[a]

Species for which acquired resistance may be a problem
Aerobic Gram-positive bacteria
Enterococcus faecium
Staphylococcus epidermidis
Staphylococcus haemolyticus
Staphylococcus hominis

Inherently resistant bacteria
All Gram-negative bacteria
Other bacteria
Chlamydia spp.
Chlamydophila spp.
Legionella pneumophila
Mycoplasma spp.

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

5.2 Pharmacokinetic properties

Absorption
Teicoplanin is administered by parenteral route (intravenously or intramuscularly). 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.

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 mL/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
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.

Elimination
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.

Special populations
- *Renal impairment:*

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.

- *Elderly patients:*

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 neonates; 58 hours for 8 years) are observed compared to adult patients.

5.3 Preclinical safety data

Following repeated parenteral administration to the rat and dog, effects on the kidney were observed and were shown to be dose-dependent and reversible. 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder for solution for injection/infusion or oral solution
Sodium chloride
Sodium hydroxide (for pH adjustment)

Solvent
Water for injections
[See Annex I - To be completed nationally]

6.2 Incompatibilities

Teicoplanin and aminoglycoside are incompatible when mixed directly and must not be mixed before injection.
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 section 6.6.
[See Annex I - To be completed nationally]

6.3 Shelf life

Shelf life of powder as packaged for sale:
3 years

Shelf life of reconstituted solution:
Chemical and physical in-use stability of the reconstituted solution prepared as recommended has been demonstrated for 24 hours at 2 to 8°C.
From a microbiological point of view, the medicinal product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Shelf life of diluted medicinal product:
Chemical and physical in-use stability of the reconstituted solution prepared as recommended has been demonstrated for 24 hours at 2 to 8°C.
From a microbiological point of view, the medicinal product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Powder as packaged for sale:
This medicinal product does not require any special storage condition.

For storage conditions of the reconstituted/diluted medicinal product, see section 6.3.
[See Annex I - To be completed nationally]

6.5 Nature and contents of container

Primary packaging:
The freeze-dried medicinal product is packaged in:
Type I, colourless glass vial of useful volume of 8 mL for 100 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium red overseal.
Type I, colourless glass vial of useful volume of 10 mL for 200 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium yellow overseal.
Type I, colourless glass vial of useful volume of 22 mL for 400 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium green overseal.

Water for injections is packaged in Type I, colourless glass ampoule.

Pack sizes:
For Targocid, powder and solvent for solution for injection/infusion or oral solution
- 1 powder vial with 1 solvent ampoule
- 5x1 powder vials with 5x1 solvent ampoules
- 10x1 powder vials with 10x1 solvent ampoules
- 25x1 powder vials with 25x1 solvent ampoules

For Targocid, powder for solution for injection/infusion or oral solution
- 1 powder vial
- 5x1 powder vials
- 10x1 powder vials
- 25x1 powder vials

Not all pack sizes may be marketed.
[See Annex I - To be completed nationally]

6.6 Special precautions for disposal and other handling

This medicinal product is for single use only.

Preparation of reconstituted solution:
- Slowly inject the entire content of the supplied solvent into the powder vial.
- Gently roll the vial between the hands until the powder is completely dissolved. If the solution does become foamy, then it should be left to stand for about 15 minutes. Only clear and yellowish solutions should be used.

The reconstituted solutions will contain 100 mg of teicoplanin in 1.5 mL, 200 mg in 3.0 mL and 400 mg in 3.0 mL.

Nominal teicoplanin content of vial	100 mg	200 mg	400 mg
Volume of powder vial	8 mL	10 mL	22 mL
Volume withdrawable from the	1.7 mL	3.14 mL	3.14 mL

solvent ampoule for reconstitution			
Volume containing nominal teicoplanin dose (extracted by 5 mL syringe and 23 G needle)	1.5 mL	3.0 mL	3.0 mL

The reconstituted solution may be injected directly or alternatively further diluted, or orally administered.

Preparation of the diluted solution before infusion:
Targocid can be administered in the following infusion solutions:
- sodium chloride 9 mg/mL (0.9%) 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% glucose solution.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

<Detailed information on this medicinal product is available on the website of {name of MS/Agency}>

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON FOR 100 mg, 200 mg and 400 mg / powder and solvent for solution for injection/infusion or oral solution

1. NAME OF THE MEDICINAL PRODUCT

Targocid and associated names (see Annex I) 100 mg powder and solvent for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 200 mg powder and solvent for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 400 mg powder and solvent for solution for injection/infusion or oral solution
[See Annex I - To be completed nationally]

teicoplanin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 100 mg teicoplanin equivalent to not less than 100,000 IU.
After reconstitution, the solution will contain 100 mg teicoplanin in 1.5 mL.

Each vial contains 200 mg teicoplanin equivalent to not less than 200,000 IU.
After reconstitution, the solution will contain 200 mg teicoplanin in 3 mL.

Each vial contains 400 mg teicoplanin equivalent to not less than 400,000 IU.
After reconstitution, the solution will contain 400 mg teicoplanin in 3 mL.

3. LIST OF EXCIPIENTS

Powder for solution for injection/infusion or oral solution also contains: sodium chloride, sodium hydroxide (for pH adjustment).
Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Powder and solvent for solution for injection/infusion or oral solution

1 powder vial and 1 solvent ampoule
5 powder vials and 5 solvent ampoules
10 powder vials and 10 solvent ampoules
25 powder vials and 25 solvent ampoules

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

For intramuscular, intravenous or oral uses

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP
Read the leaflet for the shelf life of the reconstituted medicine.

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

[To be completed nationally]

16. INFORMATION IN BRAILLE

[To be completed nationally]

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON FOR 100 mg, 200 mg and 400 mg / powder for solution for injection/infusion or oral solution

1. NAME OF THE MEDICINAL PRODUCT

Targocid and associated names (see Annex I) 100 mg powder for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 200 mg powder for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 400 mg powder for solution for injection/infusion or oral solution
[See Annex I - To be completed nationally]

teicoplanin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 100 mg teicoplanin equivalent to not less than 100,000 IU.
After reconstitution, the solution will contain 100 mg teicoplanin in 1.5 mL.

Each vial contains 200 mg teicoplanin equivalent to not less than 200,000 IU.
After reconstitution, the solution will contain 200 mg teicoplanin in 3 mL.

Each vial contains 400 mg teicoplanin equivalent to not less than 400,000 IU.
After reconstitution, the solution will contain 400 mg teicoplanin in 3 mL.

3. LIST OF EXCIPIENTS

Powder for solution for injection/infusion or oral solution also contains: sodium chloride, sodium hydroxide (for pH adjustment).

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for solution for injection/infusion or oral solution

1 powder vial
5 powder vials
10 powder vials
25 powder vials

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

For intramuscular, intravenous or oral uses

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP
Read the leaflet for the shelf life of the reconstituted medicine.

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

[To be completed nationally]

16. INFORMATION IN BRAILLE

[To be completed nationally]

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL OF POWDER VIAL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Targocid and associated names (see Annex I) 100 mg powder for injection/infusion or oral solution
Targocid and associated names (see Annex I) 200 mg powder for injection/infusion or oral solution
Targocid and associated names (see Annex I) 400 mg powder for injection/infusion or oral solution
[See Annex I - To be completed nationally]

teicoplanin
Intramuscular, intravenous or oral uses

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

100 mg
200 mg
400 mg

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL OF SOLVENT VIAL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Solvent for Targocid and associated names
[See Annex I - To be completed nationally]

Intramuscular, intravenous or oral uses

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1.5 mL
3 mL
3 mL

6. OTHER

PACKAGE LEAFLET

Package leaflet: Information for the user

Targocid and associated names (see Annex I) 100 mg powder and solvent for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 200 mg powder and solvent for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 400 mg powder and solvent for solution for injection/infusion or oral solution

Targocid and associated names (see Annex I) 100 mg powder for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 200 mg powder for solution for injection/infusion or oral solution
Targocid and associated names (see Annex I) 400 mg powder for solution for injection/infusion or oral solution
[See Annex I - To be completed nationally]

teicoplanin

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Targocid is and what it is used for

Targocid is an antibiotic. It contains a medicine called ‘teicoplanin’. It works by killing the bacteria that cause infections in your body.

Targocid is used in adults and children (including newborn babies) to treat bacterial infections of:
- the skin and underneath the skin – sometimes called ‘soft tissue’
- the bones and joints
- the lung
- the urinary tract
- the heart – sometimes called ‘endocarditis’
- the abdominal wall – peritonitis
- the blood, when caused by any of the conditions listed above

Targocid can be used to treat some infections caused by ‘*Clostridium difficile*’ bacteria in the gut. For this, the solution is taken by mouth.

2. What you need to know before you are given Targocid

Do not use Targocid if:
- you are allergic to teicoplanin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Targocid if:
- you are allergic to an antibiotic called 'vancomycin'
- you have a flushing of your upper part of your boby (red man syndrome)
- you have a decrease in platelet count (thrombocytopenia)
- you have kidney problems
- you are taking other medicines which may cause hearing problems and/or kidney problems. You may have regular tests to check if your blood, kidneys and/or liver are working properly (see 'Other medicines and Targocid').

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Targocid.

Tests
During treatment you may have tests to check your kidneys and/or your hearing. This is more likely if:
- your treatment will last for a long time
- you have a kidney problem
- you are taking or may take other medicines that may affect your nervous system, kidneys or hearing.

In people who are given Targocid for a long time, bacteria that are not affected by the antibiotic may grow more than normal – your doctor will check for this.

Other medicines and Targocid
Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. This is because Targocid can affect the way some other medicines work. Also, some medicines can affect the way Targocid works.

In particular, tell your doctor, pharmacist or nurse if you are taking the following medicines:
- Aminoglycosides as they must not be mixed together with Targocid in the same injection. They may also cause hearing problems and/or kidney problems.
- amphotericin B – a medicine that treats fungal infections which may cause hearing problems and/or kidney problems
- ciclosporin – a medicine that affects the immune system which may cause hearing problems and/or kidney problems
- cisplatin – a medicine that treats malignant tumors which may cause hearing problems and/or kidney problems
- water tablets (such as furosemide) – also called 'diuretics' which may cause hearing problems and/or kidney problems.

If any of the above apply to you, (or you are not sure), talk to your doctor, pharmacist or nurse before being given Targocid.

Pregnancy, breast-feeding and fertility
If you are pregnant, think that you might be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before being given this medicine. They will decide whether or not you are given this medicine while you are pregnant. There may be a potential risk of inner ear and kidney problems.
Tell your doctor if you are breast-feeding, before being given this medicine. They will decide whether or not you can keep breast-feeding, while you are given Targocid.

Studies in animals reproduction have not shown evidence of fertility problems.

Driving and using machines
You may have headaches or feel dizzy while being treated with Targocid. If this happens, do not drive or use any tools or machines.

Targocid contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial and is essentially 'sodium-free'.

3. How to use Targocid

The recommended dose is
Adults and children (12 years and over) with no kidney problems
Skin and soft tissue, lung and urinary tract infections
- Starting dose (for the first three doses): 400 mg (this equates to 6 mg for every kilogram of body weight), given every 12 hours, by injection into a vein or muscle
- Maintenance dose: 400 mg (this equates to 6 mg for every kilogram of body weight), given once a day, by injection into a vein or muscle

Bone and joint infections, and heart infections
- Starting dose (for the first three to five doses): 800 mg (this equates to 12 mg for every kilogram of body weight), given every 12 hours, by injection into a vein or muscle
- Maintenance dose: 800 mg (this equates to 12 mg for every kilogram of body weight), given once a day hours, by injection into a vein or muscle

Infection caused by '*Clostridium difficile*' bacteria
The recommended dose is 100 to 200 mg by mouth, twice a day for 7 to 14 days.

Adults and elderly patients with kidney problems
If you have kidney problems, your dose will usually need to be lowered after the fourth day of treatment:
- For people with mild and moderate kidney problems - the maintenance dose will be given every two days, or half of the maintenance dose will be given once a day.
- For people with severe kidney problems or on haemodialysis - the maintenance dose will be given every three days, or one-third of the maintenance dose will be given once a day.

Peritonitis for patients on peritoneal dialysis
The starting dose is 6 mg for every kilogram of body weight, as a single injection into a vein, followed by:
- Week one: 20 mg/L in each dialysis bag
- Week two: 20 mg/L in every other dialysis bag
- Week three: 20 mg/L in the overnight dialysis bag.

Babies (from birth to the age of 2 months)
- Starting dose (on the first day): 16 mg for every kilogram of body weight, as an infusion through a drip into a vein.
- Maintenance dose: 8 mg for every kilogram of body weight, given once a day, as an infusion through a drip into a vein.

Children (from 2 months to 12 years)
- Starting dose (for the first three doses): 10 mg for every kilogram of body weight, given every 12 hours, by injection into a vein.
- Maintenance dose: 6 to 10 mg for every kilogram of body weight, given once a day, by injection into a vein.

How Targocid is given

The medicine will normally be given to you by a doctor or nurse.
- It will be given by injection into a vein (intravenous use) or muscle (intramuscular use).
- It can also be given as a infusion through a drip into a vein.

Only the infusion should be given in babies from birth to the age of 2 months.
To treat certain infections, the solution may be taken by mouth (oral use).

If you have more Targocid than you should
It is unlikely that your doctor or nurse will give you too much medicine. However, if you think you have been given too much Targocid or if you are agitated, talk to your doctor or nurse straight away.

If you forget to have Targocid
Your doctor or nurse will have instructions about when to give you Targocid. It is unlikely that they will not give you the medicine as prescribed. However, if you are worried, talk to your doctor or nurse.

If you stop having Targocid
Do not stop having this medicine without first talking to your doctor, pharmacist or nurse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Stop your treatment and tell your doctor or nurse straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

Uncommon (may affect up to 1 in 100 people)
- sudden life-threatening allergic reaction - the signs may include: difficulty in breathing or wheezing, swelling, rash, itching, fever, chills

Rare (may affect up to 1 in 1000 people)
- flushing of the upper body

Not known (frequency cannot be estimated from the available data)
- blistering of the skin, mouth, eyes or genitals - these may be signs of something called ‘toxic epidermal necrolysis’ or ‘Stevens-Johnson syndrome’

Tell your doctor or nurse straight away, if you notice any of the side effects above.

Tell your doctor or nurse straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

Uncommon (may affect up to 1 in 100 people)
- swelling and clotting in a vein
- difficulty in breathing or wheezing (bronchospasm)
- getting more infections than usual - these could be signs of a decrease in your blood cell count

Not known (frequency cannot be estimated from the available data)
- lack of white blood cells – the signs may include: fever, severe chills, sore throat or mouth ulcers (agranulocytosis)
- kidney problems or changes in the way your kidneys work - shown in tests
- epileptic fits

Tell your doctor or nurse straight away, if you notice any of the side effects above.

Other side effects
Talk to your doctor, pharmacist or nurse if you get any of these:

Common (may affect up to 1 in 10 people)
- Rash, erythema, pruritus
- Pain
- Fever

Uncommon (may affect up to 1 in 100 people)
- decrease in platelet count.
- raised blood levels of liver enzymes
- raised in blood levels of creatinine (to monitor your kidney)
- hearing loss, ringing in the ears or a feeling that you, or things around you are moving
- feeling or being sick (vomiting), diarrhoea
- feeling dizzy or headache

Rare (may affect up to 1 in 1,000 people)
- infection (abcess).

Not known (frequency cannot be estimated from the available data)
- problems where the injection was given - such as reddening of the skin, pain or swelling

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

5. How to store Targocid

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label of the vial after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Information about storage and the time to use Targocid, after it has been reconstituted and is ready to use, are described in the 'Practical information for healthcare professionals on preparation and handling of Targocid'.

6. Contents of the pack and other information

For Targocid, powder and solvent for solution for injection/ infusion or oral solution
What Targocid contains
- The active substance is teicoplanin. Each vial contains either 100 mg, 200 mg or 400 mg teicoplanin.
- The other ingredients are sodium chloride and sodium hydroxide in the powder; and water for injections in the solvent.

What Targocid looks like and contents of the pack
Targocid is a powder and solvent for solution for injection/infusion or oral solution. The powder is a spongy ivory coloured homogeneous mass. The solvent is a clear and colourless solution.

The powder is packaged:
- in a Type I, colourless glass vial of useful volume of 8 mL for 100 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium red overseal.
- in a Type I, colourless glass vial of useful volume of 10 mL for 200 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium yellow overseal.
- in a Type I, colourless glass vial of useful volume of 22 mL for 400 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium green overseal.

The solvent is packaged in Type I, colourless glass ampoule.

Pack size:
– 1 powder vial with 1 solvent ampoule
– 5x1 powder vials with 5x1 solvent ampoules
– 10x1 powder vials with 10x1 solvent ampoules
– 25x1 powder vials with 25x1 solvent ampoules.

Not all pack sizes may be marketed.

For Targocid, powder for solution for injection/infusion or oral solution

What Targocid contains
- The active substance is teicoplanin. Each vial contains either 100 mg, 200 mg or 400 mg teicoplanin.
- The other ingredients are sodium chloride and sodium hydroxide.

What Targocid looks like and contents of the pack
Targocid is a powder for solution for injection/infusion or oral solution.
The powder is spongy, ivory and coloured homogeneous mass.

The powder is packaged:
- in a Type I, colourless glass vial of useful volume of 8 mL for 100 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium red overseal.
- in a Type I, colourless glass vial of useful volume of 10 mL for 200 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium yellow overseal.
- in a Type I, colourless glass vial of useful volume of 22 mL for 400 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium green overseal.

Pack size:
– 1 powder vial
– 5x1 powder vials
– 10x1 powder vials
– 25x1 powder vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
[See Annex I - To be completed nationally]

Manufacturer
[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria, Belgium, Bulgaria, Czech Republic, Denmark, France, Germany, Greece, Hungary, Ireland, Luxemburg, Malta, Netherlands, Poland, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom: Targocid
Italy, Portugal : Targosid

This leaflet was last revised in {MM/YYYY}.
[To be completed nationally]

The following information is intended for medical or healthcare professionals only:

Practical information for healthcare professionals on preparation and handling of Targocid.

This medicine is for single use only.

Method of administration
The reconstituted solution may be injected directly or alternatively further diluted.
The injection will be given either as a bolus over 3 to 5 minutes or as a 30-minutes infusion.
Only the infusion should be given in babies from birth to the age of 2 months.
The reconstituted solution may also be given by mouth.

Preparation of reconstituted solution
- Slowly inject the entire content of the supplied solvent into the powder vial.
- Gently roll the vial between the hands until the powder is completely dissolved. If the solution does become foamy, then it should be left to stand for about 15 minutes.

The reconstituted solutions will contain 100 mg of teicoplanin in 1.5 mL, 200 mg in 3.0 mL and 400 mg in 3.0 mL.
Only clear and yellowish solutions should be used.
The final solution is isotonic with plasma and has a pH of 7.2-7.8.

Nominal teicoplanin content of vial	100 mg	200 mg	400 mg
Volume of powder vial	8 mL	10 mL	22 mL
Volume withdrawable from the solvent ampoule for reconstitution	1.7 mL	3.14 mL	3.14 mL
Volume containing nominal teicoplanin dose (extracted by 5 mL syringe and 23 G needle)	1.5 mL	3.0 mL	3.0 mL

Preparation of the diluted solution before infusion
Targocid can be administered in the following infusion solutions:
- sodium chloride 9 mg/mL (0.9%) 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% glucose solution.

Shelf life of reconstituted solution
Chemical and physical in-use stability of the reconstituted solution prepared as recommended has been demonstrated for 24 hours at 2 to 8°C.

From a microbiological point of view, the medicine should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Shelf life of diluted medicine

Chemical and physical in-use stability of the reconstituted solution prepared as recommended has been demonstrated for 24 hours at 2 to 8°C.

From a microbiological point of view, the medicine should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Disposal
Any unused medicine or waste material should be disposed of in accordance with local requirements.