VI.2. ELEMENTS FOR A PUBLIC SUMMARY

VI.2.1. Overview of disease epidemiology

Teicoplanin is a glycopeptide antibiotic, indicated in potentially serious infections due to bacteria called "Gram-positive bacteria" including those which cannot be treated with other antimicrobial drugs. These bacteria can cause significant morbidity (unhealthy state) and mortality especially in the health care setting.

Teicoplanin is used to treat severe bacterial infections of the skin and underneath the skin, the bones and joints, the lung, the urinary tract, the heart, the abdominal wall and the blood when caused by one of these conditions.

VI.2.2. Summary of treatment benefits

Data from the initial program of development and decades of extended clinical experience have shown that teicoplanin administered by parenteral route is effective in the treatment of severe infections due to specific bacteria called "Gram-positive bacteria" either in the hospital or in an outpatient setting and in populations including neonates, children, adults and elderly. The main target infection sites for teicoplanin treatment include skin and soft tissue infections (skin and underneath the skin) bone and joint infections, pneumonia (lung infection), bloodstream infections (bacteremia, sepsis including urosepsis) and infective endocarditis (infection of the heart). Teicoplanin has also proved effective in peritonitis (infection of the peritoneum, the thin tissue that lines the inner wall of the abdomen and covers most of the abdominal organs) associated to continuous ambulatory peritoneal dialysis (CAPD). Moreover, teicoplanin administered orally has been successfully used in antibiotic-associated diarrhea caused by bacteria named *Clostridium difficile*.

VI.2.3. Unknowns relating to treatment benefits

Teicoplanin is a well-established antibiotic, on the market since 1988. There is no unknowns identified related to treatment benefits. However bacteria susceptibility to antibiotics changes over time and by country. Periodical assessments are published to support health care professional in their day to day practice.

VI.2.4. Summary of safety concerns

Table 4 - Important identified risks

Risk	What is known	Preventability
Severe allergic reactions [*Severe hypersensitivity reactions including angioedema and anaphylactic shock*]	Some patients may present sudden severe signs of allergy such as trouble breathing or swelling of the tongue.	Patients with a history of severe allergic reactions to teicoplanin or to another drug named vancomycin should not receive teicoplanin

Risk	What is known	Preventability
Low blood platelet count [*Thrombocytopenia*]	This drug may cause a decrease in blood platelet count	Platelet counts should be performed periodically during treatment for early detection of platelet decrease.
Kidney disease [*Renal Failure*]	Like other drugs of the same family, teicoplanin may cause kidney problems, especially when used in patients receiving other drugs causing kidney problems	Dose should be adapted in case of preexisting kidney problem. Renal function should be monitored periodically during treatment.
Hearing loss [*Ototoxicity*]	Like other drugs of the same family, teicoplanin may cause hearing deficiency especially when used in patients receiving other drugs causing hearing problems	Special attention to hearing problems should be paid to patients receiving prolonged treatment or other drugs causing hearing problems or patients with a kidney problem
Severe cutaneous adverse reactions [*Severe skin reactions (Toxic Epidermal Necrolysis, Stevens-Johnson Syndrome and exfoliative dermatitis*)]	The drug may cause severe illness with blistering of the skin, mouth, eyes and genitals	The treatment should be immediately stopped when serious skin reactions such as blistering and pealing of the skin occur.
Flushing of the upper body [*Red man Syndrome*]	In rare patients, the drug may cause during the infusion a flushing of the upper body	The drug should better be infused during 30 min than administered through a bolus. Stopping or slowing the infusion stop the reaction

Table 5 - Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Hearing loss or renal disease in fetus of pregnant women receiving teicoplanin [*Harm in fetus (eg, ototoxicity/ nephrotoxicity)]*	Although there are limited data on the use of teicoplanin in pregnant women, fetus of pregnant women receiving teicoplanin may be at an increased risk of developing hearing or renal problems.
Development of resistance to antibiotics *[Development of drug resistant strains}*	Teicoplanin is an antibiotic and bacteria susceptibility to antibiotics changes over time and by country/region. Therefore, there may be development of resistance to teicoplanin in treating bacteria.

Table 6 - Missing information

Risk	What is known
Limited information on safe use of 24 mg/Kg/day starting dose [*Safety of 24 mg/Kg/day loading dose regimen*]	There are limited information about the dose of 24 mg/kg/day used to start the treatment of infections of bones/joints and heart. This high dose may lead to a higher risk of renal problems or other adverse reactions. Patients should be carefully monitored for these events
Use in lactating women *[use in breast-feeding women]*	As it is unknown whether teicoplanin is excreted in human milk, the treating doctor should decide whether teicoplanin and breastfeeding should be continued or discontinued.

VI.2.5. Summary of additional risk minimization measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimizing them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimization measures.

This medicine has no additional risk minimization measures.

VI.2.6. Planned post authorization development plan

Table 7 - List of studies in post-authorization development plan

Study/activity (including study number)	Objectives	Safety concerns/efficacy issue addressed	Status	Planned date for submission of (interim and) final results
Prospective, observational cohort, evaluating the incidence of nephrotoxicity, and other adverse events of interest, in patients treated with the higher recommended teicoplanin loading dose (12mg/kg twice a day), and comparison with external historical comparator data	To determine the incidence of nephrotoxicity and secondary endpoints (i.e. hepatotoxicity, thrombocytopenia, hearing and balance disorders) associated with a higher loading dose of teicoplanin of 12mg/kg twice a day.	Primary Safety Endpoint: Nephrotoxicity, Secondary Safety Endpoints: Hepatotoxicity, thrombocytopenia, hearing and balance disorders, and additional renal endpoints such as renal failure	Protocol under PRAC review	Final study report plannedQ3-2018

This study is a condition of the marketing authorization.

VI.2.7. Summary of changes to the RMP over time

Table 8 - Summary of changes to the RMP over time

Version	Date	Safety concerns	Comment
1.1	Jun-2014	Use in breastfeeding women	Added as missing information as per Reference Member State (RMS) request
1.2	Sep-2014	Development of drug resistant strains	Added as potential risk as per Reference Member State (RMS) request
1.3	Nov-2014	All	Criteria for judging success of proposed routine risk minimization measures amended as follows: "Number and severity of spontaneous reports overtime", and assessments planned at time of PSURs, as per RMS request. In addition, the PASS protocol (latest version) has been appended in *Annex 6*

RMS: Reference Member State.