Summary of risk management plan for <Teicoplanin Bradex 200 mg powder and solvent for solution for injection/infusion or oral solution> and <Teicoplanin Bradex 400 mg powder and solvent for solution for injection/infusion or oral solution>

This is a summary of the risk management plan (RMP) for <Teicoplanin Bradex 200 mg powder and solvent for solution for injection/infusion or oral solution> and <Teicoplanin Bradex 400 mg powder and solvent for solution for injection/infusion or oral solution> (hereinafter referred to as TEICOPLANIN). The RMP details important risks of TEICOPLANIN, how these risks can be minimised, and how more information will be obtained about TEICOPLANIN's risks and uncertainties (missing information).

TEICOPLANIN's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how TEICOPLANIN should be used.

I. The medicine and what it is used for

TEICOPLANIN is authorised for 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 and as an alternative oral treatment for Clostridium difficile infection-associated diarrhoea and colitis (see SmPC for the full indication). It contains teicoplanin as the active substance and it is given by intravenous or intramuscular administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of TEICOPLANIN, together with measures to minimise such risks and the proposed studies for learning more about TEICOPLANIN's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of TEICOPLANIN is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of TEICOPLANIN are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of TEICOPLANIN. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the longterm use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	Safety of 24 mg/Kg/day loading dose regimen

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of TEICOPLANIN.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for TEICOPLANIN.