Part VI: Summary of the risk management plan

Summary of risk management plan for Tigecycline Norameda 50 mg powder for solution for infusion

This is a summary of the risk management plan (RMP) for Tigecycline Norameda 50 mg powder for solution for infusion. The RMP details important risks of Tigecycline Norameda, how these risks can be minimised, and how more information will be obtained about risks and uncertainties (missing information).

Tigecycline Norameda 50 mg powder for solution for infusion Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tigecycline should be used.

I. The medicine and what it is used for

Tigecycline Norameda 50 mg powder for solution for infusion is a semisynthetic derivative of minocycline with a broad spectrum of antibacterial activity, including inhibition of Gram-positive, Gram-negative, atypical, and anaerobic bacteria.
Tigecycline Norameda is a medicine used for the treatment of the following infections: (adult and paediatric - from the age of eight years) complicated skin and soft tissue infections (cSSTI), excluding diabetic foot infections, and complicated intra-abdominal infections (cIAI). Tigecycline Norameda should be used only in situations where other alternative antibiotics are not suitable. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

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

Important risks of Tigecycline Norameda 50 mg powder for solution for infusion, together with measures to minimise such risks for learning more about 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 (PL / PIL) 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, including signal detection, 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 Tigecycline Norameda is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tigecycline Norameda 50 mg powder for solution for infusion 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 Tigecycline Norameda. 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 long-term use of the medicine).

List of important risks and missing information	
Important identified risks	• Thrombocytopenia • Hepatotoxicity • Anaphylaxis • Pancreatitis • Superinfection
Important potential risks	• QTc prolongation/ Torsades de pointes • *Clostridium difficile*-associated diarrhoea and pseudomembranous colitis • Lack of efficacy
Missing information	• Use in paediatric patients aged less than 8 years • Use in pregnant and breast-feeding women • Use in patients on immunosuppressant therapy • Use in patients with neutropenia

II.B Summary of important risks

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

II.C Post-authorisation development plan

Not applicable.

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

There are no studies which are conditions of the marketing authorisation / renewal or specific obligation of Tigecycline Norameda 50 mg powder for solution for infusion.

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

There are no studies required for Tigecycline Norameda 50 mg powder for solution for infusion.