Summary of risk management plan for Tigecycline Accord 50 mg powder for solution for infusion (tigecycline)

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

Tigecycline Accord 50 mg powder for solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tigecycline Accord 50 mg powder for solution for infusion should be used.

This summary of the RMP for Tigecycline Accord 50 mg powder for solution for infusion should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Tigecycline Accord 50 mg powder for solution for infusion's RMP.

I. The medicine and what it is used for

Tigecycline is indicated in adults and in children from the age of eight years for the treatment of the following infections):

- Complicated skin and soft tissue infections (cSSTI), excluding diabetic foot infections
- Complicated intra-abdominal infections (cIAI).

Tigecycline Accord 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. It contains tigecycline as the active substance and it is given by intravenous infusion over 30 to 60 minutes. Tigecycline should be preferably administered over a 60-minute length of infusion in paediatric patients.

Further information about the evaluation of C Tigecycline Accord 50 mg powder for solution for infusion benefits can be found in Tigecycline's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage. https://www.ema.europa.eu/en/medicines/human/EPAR/tigecycline-accord

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

Important risks of Tigecycline Accord 50 mg powder for solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Tigecycline Accord 50 mg powder for solution for infusion'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, including PSUR assessment and signal management activity, 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 Accord 50 mg powder for solution for infusion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tigecycline Accord 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 taken. 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 Accord 50 mg powder for solution for infusion. 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);

Important identified risks	• Thrombocytopenia • Hepatotoxicity • Anaphylaxis/anaphylactoid skin reactions • 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 with neutropenia • Use in patients on immunosuppressant therapy

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 Tigecycline Accord 50 mg powder for solution for infusion.

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

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