

## Part VI: Summary of the risk management plan

### Summary of risk management plan for GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/infusion (gentamicin)

This is a summary of the risk management plan (RMP) for GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/infusion. The RMP details important risks of GENTAMICIN PHARMEXON Consulting 40 mg/ml solution for injection/infusion, how these risks can be minimised and how more information will be obtained about risks and uncertainties (missing information).

GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/infusion's summary of product characteristics (SmPC) and its package leaflet gives essential information to healthcare professionals and patients on how GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/infusion should be used.

Important new concerns or changes will be included in updates of GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/infusion's RMP.

#### I. The medicine and what it is used for

GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/infusion is indicated in adults and children from birth for the treatment of severe infections due to bacteria susceptible to gentamicin when less toxic antimicrobial agents are not effective (see SmPC for the full indication).

It contains gentamicin as the active substance and it is given by the intravenous and intramuscular route.

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

Important risks of GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/infusion, together with measures to minimise such risks and the proposed studies for learning more about GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/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 medicine's legal status (with prescription) can help to minimise risks.

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

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

## ***II.A List of important risks and missing information***

Important risks of GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/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 causal link with the use of GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/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);

<b>List of important risks and missing information</b>	
Important identified risks	None
Important potential risks	None
Missing information	None

## ***II.B Summary of important risks***

Not applicable.

## ***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 GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/infusion.

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

There are no studies required for GENTAMICIN PHARMEXON Consulting 40 mg/ml, solution for injection/infusion.