Part VI: Summary of the risk management plan

Summary of risk management plan for
Meriofer 75-150-900 IU, powder and solvent
for solution for injection

This is a summary of the risk management plan (RMP) for Meriofert 75-150-900 IU, powder and solvent for solution for injection (hMG). The RMP details important risks of the product, how these risks can be monitor and minimized, and how more information will be obtained about Meriofert 75-150-900 IU, powder and solvent for solution for injection's risks and uncertainties (missing information).

Meriofert 75-150-900 IU, powder and solvent for solution for injection 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

I. The medicine and what it is used for

Meriofert is authorised for

- **Ovulation induction:** for the induction of ovulation in amenorrhoeic or anovulatory women who have not responded to treatment with clomiphene citrate.
- **Controlled ovarian hyperstimulation (COH)** within a medically assisted reproduction technology (ART): induction of multiple follicular development in women undergoing assisted reproduction techniques such as in vitro fertilization (IVF).

(see SmPC. It contains menotrophin <INN> as the active substance and it is given either by subcutaneous (sc) or intramuscular (im)).

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

Important risks of Meriofert Set together with measures to minimise such risks and the proposed studies for learning more about Meriofert Set'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 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 Meriofert Set 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 Meriofert Set. 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).

II.B Summary of important risks

Summary of safety concerns	
Important identified risks	none
Important potential risks	none
Missing information	none

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 authorization or specific obligation of Menotrophin 75-150-900 IU.

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

There are no other studies required for Menotrophin 75-150-900 IU.