Part VI: Summary of the risk management plan

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

This is a summary of the risk management plan (RMP) for Meriofert 75-150 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 IU, powder and solvent for solution for injection's risks and uncertainties (missing information).

Meriofert 75-150 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

Not applicable.

II.A List of important risks and missing information

Not applicable.

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 authorization or specific obligation of Menotrophin 75-150 IU.

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

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