Part VI: Summary of the risk management plan

Summary of risk management plan (RMP) for MENOGON (menotrophin)/MENOPUR (menotrophin highly-purified).

This is a summary of the RMP for MENOGON/MENOPUR. The RMP details important risks of MENOGON/MENOPUR, and how more information will be obtained about MENOGON/MENOPUR risks and uncertainties (missing information).

The summary of product characteristics (SmPC) and it is the patient information leaflet (PIL) give essential information to healthcare professionals and patients on how MENOGON/MENOPUR should be used.

Important new concerns or changes to the current ones will be included in updates of the MENOGON/MENOPUR RMP.

I. The medicine and what it is authorised for

MENOGON/MENOPUR is authorised for ovulation induction (OI), controlled ovarian stimulation (COH) in assisted reproductive technology (ART) and follicular development in hypogonadotrophic hypogonadism (HH). See SmPC for the full indication. It contains menotrophin as the active substance and is administered by subcutaneous injection.

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

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the 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 PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

In the case of MENOGON/MENOPUR, these above routine measures and activities are in effect. There are no additional risk minimisation activities to minimise or further characterise the risks.

II.A List of important risks and missing information

Important risks 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 the product. 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).

The safety concerns previously included in the risk management plan for MENOGON/MENOPUR are removed with this version following re-examination in light of revision 2 of GVP Module V.

List of important risks and missing information in the RMP for MENOGON/MENOPUR	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable.

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

There are no studies that are conditions of the marketing authorisation or specific obligations for MENOGON/MENOPUR.

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

No studies are required.