Summary of the Risk Management Plan (RMP)

REKOVELLE (follitropin delta)

Active substance(s) (INN or common name):	Follitropin delta
Product(s) concerned (brand name(s))	Rekovelle
Name of Marketing Authorisation Holder or Applicant	Ferring AG Baarermatte 6340 Baar Switzerland
RMP version	7.0

Disclaimer:

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of REKOVELLE is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorisation.

Please note that the reference document which is valid and relevant for the effective and safe use of REKOVELLE in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorised by Swissmedic. Ferring AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of REKOVELLE.

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Part VI: Summary of the risk management plan for REKOVELLE (Recombinant FSH)

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

REKOVELLE's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how REKOVELLE should be used.

This summary of the RMP for REKOVELLE 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 REKOVELLE's RMP.

I. The medicine and what it is used for

REKOVELLE is authorised for controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies such as an in vitro fertilisation or intracytoplasmic sperm injection cycle (see SmPC for the full indication). It contains recombinant FSH as the active substance and it is given by subcutaneous injection.

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

Important risks of REKOVELLE, together with measures to minimise such risks and the proposed studies for learning more about REKOVELLE'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.

If important information that may affect the safe use of REKOVELLE is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of REKOVELLE 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 REKOVELLE. 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);

List of important risks and missing information:

Important identified risks	None
Important potential risks	None
Missing information	Experience with follitropin delta in the long GnRH agonist protocol

II.B Summary of important risks

No risks are classified as important potential or important identified risks.

Summary of missing presentation is presented below:

Summary of missing information

Missing information: Experience with follitropin delta in the long GnRH agonist protocol
Evidence source: Clinical trial experience. Population in need of further characterisation: There is no clinical trial experience with REKOVELLE in the long GnRH agonist protocol. Data on the efficacy and safety of follitropin delta in a long GnRH agonist protocol are currently collected in two trials, namely trial 000289 which applies a long GnRH agonist protocol in all patients and one comparative trial 000304 that compares the efficacy and safety of follitropin delta in a long GnRH agonist versus GnRH antagonist protocol.

II.C Post-authorisation development plan

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

There are no studies which are condition of the marketing authorisation or specific obligation of REKOVELLE.

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

There are no studies required for REKOVELLE.