Part VI: Summary of the Risk Management Plan

Summary of the Risk Management Plan for Gonal-f®

This is a summary of the Risk Management Plan (RMP) for Gonal-f®. The RMP details important risks of Gonal-f®, how these risks can be minimized, and how more information will be obtained about Gonal-f® risks and uncertainties (missing information).

Gonal-f® summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Gonal-f® should be used.

This summary of the RMP for Gonal-f® 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 Gonal-f® RMP.

I. The Medicine and What it is used for

Gonal-f® is authorized:

In adult women:

- Anovulation [including polycystic ovarian syndrome (PCOS)] in women who have been unresponsive to treatment with clomiphene citrate.
- Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as *in vitro* fertilisation (IVF), gamete intra-fallopian transfer (GIFT) and zygote intra-fallopian transfer (ZIFT).
- Gonal-f® in association with a luteinising hormone (LH) preparation is recommended for the stimulation of follicular development in women with severe LH and FSH deficiency.

In adult men:

- Gonal-f® is indicated for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotrophic hypogonadism with concomitant human Chorionic Gonadotrophin (hCG) therapy.

It contains follitropin alfa as the active substance and it is given by subcutaneous administration.

Further information about the evaluation of Gonal-f®'s benefits can be found in Gonal-f®'s EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage link to the product's EPAR summary landing page on the EMA website.

II. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of Gonal-f®, together with measures to minimize such risks and the proposed studies for learning more about Gonal-f®'s risks, are outlined below.

Measures to minimize 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 authorized 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 minimize its risks.

Together, these measures constitute routine risk minimization measures. In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report (PSUR) assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Gonal-f® is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Gonal-f® are risks that need special risk management activities to further investigate or minimize 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 Gonal-f®. 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).

There are no important identified or important potential risks or missing information

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of Important Risks

There are no important identified or important potential risks and missing information for the

product.

II.C Post-Authorization Development Plan

II.C.1 Studies which are Conditions of the Marketing Authorization

There are no studies which are conditions of the Marketing Authorization or specific obligation of Gonal-f®.

II.C.2 Other Studies in the Post-Authorization Development Plan

There are no studies required for Gonal-f®.