

Part VI: Summary of the risk management plan

Summary of risk management plan for Ganirelix Gedeon Richter 0.25 mg/0.5 mL solution for injection in pre-filled syringe (ganirelix acetate)

This is a summary of the risk management plan (RMP) for Ganirelix Gedeon Richter 0.25 mg/0.5 mL solution for injection in pre-filled syringe. The RMP details important risks of Ganirelix Gedeon Richter and how more information will be obtained about Ganirelix Gedeon Richter's risks and uncertainties (missing information).

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

This summary of the RMP for Ganirelix Gedeon Richter 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 how Ganirelix Gedeon Richter's RMP.

I. The medicine and what it is used for

Ganirelix Gedeon Richter is authorised for the prevention of premature luteinising hormone (LH) surges in women undergoing controlled ovarian hyperstimulation (COH) for assisted reproduction techniques (ART) (see SmPC for the full indication). It contains ganirelix acetate as the active substance and it is given by subcutaneous administration.

Further information about the evaluation of Ganirelix Gedeon Richter's benefits can be found in Ganirelix Gedeon Richter's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:

<https://www.ema.europa.eu/en/medicines/human/EPAR/ganirelix-gedeon-richter>

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

Important risks of Ganirelix Gedeon Richter, together with measures to minimise such risks and the proposed studies for learning more about Ganirelix Gedeon Richter'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, 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 Ganirelix Gedeon Richter is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Ganirelix Gedeon Richter 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 Ganirelix Gedeon Richter. 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);

Summary of safety concerns	
Important identified risks	Hypersensitivity reaction Injection site reactions
Important potential risks	None
Missing information	Patients with renal or hepatic impairment Pregnant and lactating women Women with a history or current Type I hypersensitivity

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 authorisation or specific obligation of Ganirelix Gedeon Richter.

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

There are no studies required for Ganirelix Gedeon Richter.