Summary of risk management plan for

Progedex 25mg Injektionslösung in einer Fertigspritze

(progesterone)

This is a summary of the risk management plan (RMP) for Progedex 25mg Injektionslösung in einer Fertigspritze. The RMP details important risks, how these risks can be minimised, and how more information will be obtained about risks and uncertainties (missing information).

Summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Progedex 25mg Injektionslösung in einer Fertigspritze should be used.

Important new concerns or changes to the current ones will be included in updates of Progedex 25mg Injektionslösung in einer Fertigspritze's RMP.

I. The medicine and what it is used for

Progedex 25mg Injektionslösung in einer Fertigspritze is authorized for luteal phase support in assistive reproductive technology treatment (ART) in infertile women, who cannot use or are unable to tolerate vaginal preparations.
It contains progesterone as the active substance and it is given subcutaneously by the patient herself after instruction or by a healthcare professional or a doctor.

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

Important risks of Progedex 25mg Injektionslösung in einer Fertigspritze , together with measures to minimize such risks and the proposed studies for learning more about Progedex 25mg Injektionslösung in einer Fertigspritz'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 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 minimization 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.

II.A List of important risks and missing information

Important risks of Progedex 25mg Injektionslösung in einer Fertigspritze 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 Progedex 25mg Injektionslösung in einer Fertigspritze . 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)

II.B Summary of important risks

Important Identified Risks	None
Important Potential Risks	None
Missing information	None

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 authorisation or specific obligation of Progedex 25mg Injektionslösung in einer Fertigspritze.

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

There are no studies required for Progedex 25mg Injektionslösung in einer Fertigspritze.