Part VI: Summary of the Risk Management Plan

Summary of the Risk Management Plan for progesterone vaginal gel

The RMP details important risks of progesterone vaginal gel, how these risks can be minimized, and how more information will be obtained about progesterone vaginal gel‘s risks and uncertainties (missing information).

Progesterone vaginal gel’s SmPC and its package leaflet give essential information to healthcare professionals and patients on how progesterone vaginal gel should be used.

Important new concerns or changes to the current ones will be included in updates of progesterone vaginal gel‘s RMP.

I The Medicine and What it is used for

Progesterone vaginal gel is authorized for progesterone supplementation of the luteal phase in adults as part of an ART procedure. It contains progesterone as the active substance, and it is given by vaginal administration.

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

Important risks of progesterone vaginal gel, together with measures to minimize such risks and the proposed studies for learning more about progesterone vaginal gel‘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 analysed, including Periodic Safety Update Reports 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 progesterone vaginal gel 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 progesterone vaginal gel. 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	• 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 progesterone vaginal gel.

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

There are no studies required for progesterone vaginal gel.