Part IV

IV Summary of the risk management plan for

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

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

I. The medicine and what it is used for

Gynoflor is authorised for restoration of lactobacilli flora after local and/or systemic treatment with anti-infective or chemotherapy agents of vaginal infections in premenopausal women and for Treatment of atrophic vaginitis in postmenopausal or perimenopausal women (see SmPC for the full indication). It contains estriol and viable Lactobacillus acidophilus as the active substance and it is given by vaginal administration.

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

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

II.A List of important risks and missing information

Important risks of Gynoflor 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 Gynoflor. 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	Endometrial hyperplasia, Breast, uterine and ovarian cancer, Risk of venous thromboembolism, Ischaemic troke and coronary artery disease, Fluid retention or increase of plasma tri I cerides
Missing information	None

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

Il.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 Gynoflor.

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

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