Part VI: Summary of the risk management plan

Summary of risk management plan for {Invented name} estradiol 0,01 mg vaginal tablet (estradiol)

This is a summary of the risk management plan (RMP) for {Invented name} estradiol 0,01 mg vaginal tablet. The RMP details important risks of {Invented name} estradiol 0,01 mg vaginal tablet, how these risks can be minimised, and how more information will be obtained about {Invented name} estradiol 0,01 mg vaginal tablet's risks and uncertainties (missing information).
{Invented name} estradiol 0,01 mg vaginal tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how {Invented name} estradiol 0,01 mg vaginal tablet should be used.

I. The medicine and what it is used for

{Invented name} is authorised for the treatment of vaginal atrophy due to oestrogen deficiency in postmenopausal women. Experience in treating women older than 65 years is limited. It contains estradiol as the active substance and it is given vaginally by use of an applicator.

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

Important risks of {Invented name} estradiol 0,01 mg vaginal tablet., together with measures to minimise such risks and the proposed studies for learning more about {Invented name} estradiol 0,01 mg vaginal tablet'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, 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 {Invented name} estradiol 0,01 mg vaginal tablet 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 {Invented name} estradiol 0,01 mg vaginal tablet. 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.

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

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 {Invented name} estradiol 0,01 mg vaginal tablet.

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

There are no studies required for {Invented name} estradiol 0,01 mg vaginal tablet.