Part VI – Summary of the risk management plan by product

Summary of risk management plan for Ulipristal acetate.

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

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

Important new concerns or changes to the current ones will be included in updates of Femke/Ulipristal Mylan's RMP.

I. The medicine and what it is used for

Femke/Ulipristal Mylan is authorised for emergency contraception within 120 hours (5 days) of unprotected sex or contraceptive failure (such as a tear in a condom during sex). It contains ulipristal acetate as the active substance and it is taken by mouth.

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

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

II.A List of important risks and missing information

Important risks of Femke/Ulipristal Mylan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Femke/Ulipristal Mylan. 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	There are no important identified risks for Femke/Ulipristal Mylan.
Important potential risks	- Effects on pregnancy maintenance/off label use - Risk of incomplete abortion and heavy bleeding - Effects on foetus and newborns - Risk of ectopic pregnancy - Concomitant use of CYP3A4 inducers - Liver effects - Delayed menstrual period >60 days / amenorrhea - Ovarian cysts
Missing information	- Effect of concomitant use of progestin-only contraception - Effect in patients with severe asthma treated by oral glucocorticoid - Effects in women with impaired liver function

II.B Summary of important risks

Effects on pregnancy maintenance/off label use	
Risk minimisation measures	Routine risk minimisation measures: Warning in sections 4.4 and 4.6 of the SmPC. Warning in sections 1,2 and 3 of PIL. Additional risk minimization measures: None.
Additional pharmacovigilance activities	Additional pharmacovigilance activities: A pregnancy registry to collect clinical follow-up information and outcomes of pregnancies resulting from Femke/Ulipristal Mylan failure or pregnancies inadvertently exposed to Femke/Ulipristal Mylan.

Risk of incomplete abortion and heavy bleeding	
Risk minimisation measures	Routine risk minimisation measures: Warning in section 4.4 and information in section 4.8 of SmPC. Warning in section 2 of PIL. Additional risk minimization measures: None.

Additional pharmacovigilance activities	Additional pharmacovigilance activities: A pregnancy registry to collect clinical follow-up information and outcomes of pregnancies resulting from Femke/Ulipristal Mylan failure or pregnancies inadvertently exposed to Femke/Ulipristal Mylan.

Effects on foetus and newborn	
Risk minimisation measures	Routine risk minimisation measures: Information in sections 4.6 and 5.3 of SmPC. Additional risk minimization measures: None.
Additional pharmacovigilance activities	Additional pharmacovigilance activities: A pregnancy registry to collect clinical follow-up information and outcomes of pregnancies resulting from Femke/Ulipristal Mylan failure or pregnancies inadvertently exposed to Femke/Ulipristal Mylan.

Risk of ectopic pregnancy	
Risk minimisation measures	Routine risk minimisation measures: Warning in section 4.4 of SmPC. Warning in section 2 of PIL. Additional risk minimization measures: None.
Additional pharmacovigilance activities	Additional pharmacovigilance activities: A pregnancy registry to collect clinical follow-up information and outcomes of pregnancies resulting from Femke/Ulipristal Mylan failure or pregnancies inadvertently exposed to Femke/Ulipristal Mylan.

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 Femke/Ulipristal Mylan.

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

A pregnancy exposure registry to assess clinical follow-up and outcomes of pregnancies exposed to Femke/Ulipristal Mylan

The aim of this pregnancy registry is to collect all data about pregnancy outcome in women exposed to ulipristal for any reason e.g. unrecognized pregnancy before intake or product failure.

The primary objective of this pregnancy registry is to collect all data about pregnancy and pregnancy outcome in women exposed to ulipristal acetate 30mg for any reason, e.g. unrecognized pregnancy before intake or product failure.

The secondary objective is to monitor the important identified risks “Effects on pregnancy maintenance/off-label use”, “Risk of incomplete abortion and heavy bleeding”, “Effects on foetus and newborns” and “Risk of ectopic pregnancy”.