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 <Product name>. The RMP details important risks of <Product name>, how these risks can be minimised, and how more information will be obtained about <Product name>'s risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of <Product name>'s RMP.

I. The medicine and what it is used for

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

II.A List of important risks and missing information

Important risks of <Product name> 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 <Product name>. 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 <Product name>.
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 exposure registry to assess clinical follow-up and outcomes of pregnancies exposed to <Product name>.

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 exposure registry to assess clinical follow-up and outcomes of pregnancies exposed to <Product name>.

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 exposure registry to assess clinical follow-up and outcomes of pregnancies exposed to <Product name>.

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 exposure registry to assess clinical follow-up and outcomes of pregnancies exposed to <Product name>.

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 <Product name>.

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 <Product name>.

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.

Specific safety concerns that will be addressed through this pregnancy registry are 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”.