Part VI: Summary of the risk management plan

Summary of risk management plan for drospirenone and ethinylestradiol film-coated tablets*

** See end of the Part VI: Summary of the risk management plan for a list of products referenced in this RMP with the relevant procedure numbers*

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

Drospirenone and ethinylestradiol film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how drospirenone and ethinylestradiol film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of drospirenone and ethinylestradiol film-coated tablets' RMP.

I. The medicine and what it is used for

Drospirenone and ethinylestradiol film-coated tablets are authorised for oral contraception (see SmPC for the full indication). It contains drospirenone and ethinylestradiol as the active substances and it is given orally.

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

Important risks of drospirenone and ethinylestradiol film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about drospirenone and ethinylestradiol film-coated tablets' 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 the case of drospirenone and ethinylestradiol film-coated tablets, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

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*.

II.A List of important risks and missing information

Important risks of drospirenone and ethinylestradiol film-coated tablets 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 drospirenone and ethinylestradiol film-coated tablets. 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	#1 Venous thromboembolism
	#2 Arterial thromboembolism
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important Identified Risk 1. Venous thromboembolism	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.1, 4.3, 4.4, 4.6 and 4.8 PL sections 2 and 4 Prescription only medicine. Additional risk minimisation measures: Checklist for prescribers Information card for women

Important Identified Risk 2. Arterial thromboembolism	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.3, 4,4 and 4.8 PL sections 2 and 4 Prescription only medicine. Additional risk minimisation measures: Checklist for prescribers Information card for women

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 drospirenone and ethinylestradiol film-coated tablets.

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

There are no studies required for drospirenone and ethinylestradiol film-coated tablets.

*List of products referenced in this RMP:

Alexette, Amarosa, Amarosa Continuous, Aneea, Aranka, Arankelle, Arankelle Continuous, Belusha, Bertelle, Daylette, Daylla, Deren, Deren Continuous, Drosana 20, Drosana 30, Drospirenone/Ethinylestradiol Richter, Elvina, Elvinette, ESLARILA, Eslarila Continuous, Everissa, Federia, Federia Continuous, Fragotella, Gyndora, GYNDORA CONTINUOUS, Inkodess, Inkodess Continuous, Katul, Katul Continuous, Kylixa, Kylnetta, Kylnetta Continuous, Lovette, Lovette ED, Lucette, Lucette ED, Lulina, Maitalon, Maitalon 20, MAITALON 20/21+7, MAITALON 30, MAITALON 30/21+7, Midiana, Midiana 28, Midiana Continuous, Midiana Zilnic, Minkian, Pyrla, Rezia, Seelar, Selikyne, Svelta, Symicia, Teenia, Tentacia, Tolukim, Volina, Volina mite, Xindea, Zeelar Continuous, Zoa

*Procedure numbers:

HU/H/0263/001/DC, HU/H/0291/001/DC, HU/H/0290/001/DC, HU/H/0289/001/DC, HU/H/0288/001/DC, HU/H/0287/001/DC, HU/H/0286/001/DC, HU/H/0285/001/DC, HU/H/0284/001/DC, HU/H/0283/001/DC, HU/H/0276/001/DC, HU/H/0275/001/DC, HU/H/0274/001/DC, HU/H/0273/001/DC, HU/H/0265/001/DC, HU/H/0264/001/DC, HU/H/0263/001/DC, HU/H/0262/001/DC, HU/H/0260/001/DC, HU/H/0259/001/DC, HU/H/0258/001/DC, HU/H/0256/001/DC, HU/H/0255/001/DC, HU/H/0295/001/DC, HU/H/0294/001/DC, HU/H/0293/001/DC, HU/H/0292/001/DC, HU/H/0282/001/DC, HU/H/0281/001/DC, HU/H/0280/001/DC, HU/H/0279/001/DC, HU/H/0278/001/DC, HU/H/0277/001/DC, HU/H/0235/001/DC, HU/H/0234/001/DC, HU/H/0233/001/DC, HU/H/0357/001/DC, HU/H/0356/001/DC, National HU