Part VI: Summary of the risk management plan

Summary of risk management plan for {Invented name} **0.06 mg/0.015 mg film-coated tablet (gestodene and ethinylestradiol)**

This is a summary of the risk management plan (RMP) for {Invented name} 0.06 mg/0.015 mg film-coated tablet. The RMP details important risks of {Invented name}.0.06 mg/0.015 mg film-coated tablet, how these risks can be minimised, and how more information will be obtained about {Invented name} 0.06 mg/0.015 mg film-coated tablet's risks and uncertainties (missing information).

{Invented name} 0.06 mg/0.015 mg film-coated tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how {Invented name} 0.06 mg/0.015 mg film-coated tablet should be used.

I. The medicine and what it is used for

{Invented name} 0.06 mg/0.015 mg film-coated tablet is authorised for oral hormonal contraception (see SmPC for the full indication). It contains gestodene and ethinylestradiol as the active substances and it is given orally in 0.06 mg/0.015 mg film-coated tablets.

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

Important risks of {Invented name} 0.06 mg/0.015 mg film-coated tablet, together with measures to minimise such risks and the proposed studies for learning more about {Invented name} 0.06 mg/0.015 mg film-coated 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 the case of {Invented name} 0.06 mg/0.015 mg film-coated tablet, 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 {Invented name} 0.06 mg/0.015 mg film-coated tablet 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 {Invented name} 0.06 mg/0.015 mg film-coated 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. 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);

Summary of safety concerns	
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 section 4.3, 4.6 and 4.8* • *SmPC section 4.1, where advice is given on comparing with other combined hormonal contraceptives regarding the degree of VTE risks* • *SmPC section 4.4, where advice is given on medical examination before prescription* • *SmPC section 4.4, where advice is given on drawing woman's attention to the information of VTE* • *PL section 2, where information is given on how to recognise a blood clot* • *PL section 4, where advice is given on in the evet of which serious side effects should a patient seek medical help immediately* 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 section 4.3 and 4.8* • *SmPC section 4.4, where advice is given on drawing woman's attention to the information of ATE* • *PL section 2, where advice is given on how to recognise a blood clot* 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 {Invented name}.

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

There are no studies required for {Invented name} 0.06 mg/0.015 mg film-coated tablet.