	RISK MANAGEMENT PLAN
	Dienogest DIENOGEST, 2 mg, TABLET

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Dienogest 2 mg tablets (Dienogest)

This is a summary of the risk management plan (RMP) for **Dienogest 2 mg tablets**. The RMP details important risks of **Dienogest 2 mg tablets** and how more information will be obtained about **Dienogest 2 mg tablets** risks and uncertainties (missing information).

Dienogest 2 mg tablets's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how **Dienogest 2 mg tablets** should be used.

I. The medicine and what it is used for


Dienogest 2 mg tablets is authorised for the treatment of endometriosis (see SmPC for the full indication). It contains dienogest as the active substance and it is given by oral route.

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

Important risks of **Dienogest 2 mg tablets**, together with measures to minimise such risks and the proposed studies for learning more about **Dienogest 2 mg tablets**'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;

	RISK MANAGEMENT PLAN
	Dienogest DIENOGEST, 2 mg, TABLET

- 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.

If important information that may affect the safe use of **Dienogest 2 mg tablets** is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of **Dienogest 2 mg 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 **Dienogest 2 mg 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);

Summary of safety concerns	
Important identified risks	<ul style="list-style-type: none"> - Serious uterine bleeding - Reduction of bone mineral density
Important potential risks	<ul style="list-style-type: none"> - Depression - Bone mineral density loss in adolescents - Arterial thromboembolism - Venous thromboembolism - Ectopic pregnancy - Breast cancer - Benign and malignant liver tumours - Recurrence of cholestatic jaundice
Missing information	<ul style="list-style-type: none"> - Paediatric use - Long-term use

	RISK MANAGEMENT PLAN
	Dienogest DIENOGEST, 2 mg, TABLET

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 **Dienogest 2 mg tablets**.

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

There are no studies required for **Dienogest 2 mg tablets**.