Visanne®
(Dienogest)
EU Risk Management Plan

Summary of the Risk Management Plan

Summary of the Risk Management Plan for Visanne®(Dienogest)

This is a summary of the risk management plan (RMP) for Visanne®. There are currently no important risks of Visanne® according to the definitions given in the Good Pharmacovigilance Practices (GVP), Module V.

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

I. The Medicine and what it is used for

Visanne® is authorised for treatment of endometriosis (see SmPC for the full indication). It contains dienogest as the active substance and it is given by oral administration.

II. Risks Associated with the Medicine and Activities to Minimise or further Characterise the Risks

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, including Periodic Safety Update Report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

As none of the identified and potentioal risks of Visanne® are judged as important, there are no additional pharmacovigilance activities and risk minimization measures related to the product beyond those described above in this Section of the document.

II.A List of Important Risks and Missing Information

None of the identified and potential risks of Visanne® are considered important according to the definitions given in the GVP, Module V.

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Table 1: Summary of safety concerns

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of Important Risks

There are no important identified/potential risks or missing information included in the list of safety concerns.

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 Visanne®.

II.C.2 Other Studies in Post-authorisation Development Plan

Not applicable.