Part VI: Summary of the risk management plan

Summary of risk management plan for Malonetta (levonorgestrel/ ethinylestradiol)

This is a summary of the risk management plan (RMP) for Malonetta. The RMP details important risks of Malonetta, how these risks can be minimized, and how more information will be obtained about Malonetta's risks and uncertainties (missing information).

Malonetta's summary of product characteristics (SmPCs) and its package leaflet (PLs) give essential information to healthcare professionals (HCPs) and patients on how Malonetta should be used.

Important new concerns or changes to the current ones will be included in updates of the Malonetta's RMP.

I. The medicine and what it is used for

Malonetta, is authorized for:

Oral contraception.

The decision to prescribe Malonetta should take into consideration the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), and how the risk of VTE with Malonetta compares with other combined hormonal contraceptives (CHCs). (see SmPC for the full indication).

It contains levonorgestrel and ethinylestradiol as an active substance and it is given orally as film coated tablets (150 µg/30 µg).

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Malonetta, together with measures to minimize such risks and the proposed studies for learning more about Malonetta's risks, are outlined below.

Measures to minimize 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 authorized 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 Malonetta are risks that need special risk management activities to further investigate or minimize 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 Malonetta. 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	Venous thromboembolism (VTE)
	Arterial thromboembolism (ATE)
	Benign and malignant liver tumors
	Breast cancer
	Disturbance of liver function
	Pancreatitis
	Effects on hereditary and acquired angioedema
Important potential risks	Cervical cancer
	Worsening of endogenous depression
	Worsening of Crohn’s disease and ulcerative colitis
	Increased blood pressure
	Insulin resistance/decreased glucose tolerance
Missing information	None

II.B Summary of important risks

The safety information in the proposed product information is aligned to the reference medicinal product.

II. Post-authorization development plan

II.C.1 Studies which are conditions of the Marketing authorization

There are no studies which are conditions of the Marketing authorization or specific obligation of Malonetta.

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

There are no studies required for Malonetta.