Part VI: Summary of the risk management plan

Summary of risk management plan for Qlady film-coated tablets (Estradiol valerate and estradiol valerate/dienogest)

This is a summary of the risk management plan (RMP) for estradiol valerate and estradiol valerate/dienogest. The RMP details important risks of Qlady, how these risks can be minimised, and how more information will be obtained about estradiol valerates's and estradiol valerate /dienogest's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Qlady is indicated for:

- Oral contraception.

- Treatment of heavy menstrual bleeding in women without organic pathology who desire oral contraception. (see SmPC for the full indication).

The decision to prescribe estradiol valerate and dienogest/estradiol valerate film-coated tablets should take into consideration the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), and how the risk of VTE with estradiol valerate and dienogest/estradiol valerate film-coated tablets compares with other combined hormonal contraceptives (CHCs)

It contains estradiol valerate and dienogest as active substances, and it is given by oral route of administration.

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

Important risks of Qlady together with measures to minimise such risks and the proposed studies for learning more about estradiol valerate's and estradiol valerate/dienogest'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 estradiol valerate and dienogest/estradiol valerate, 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 Qlady are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 estradiol valerate and estradiol valerate/dienogest. 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)
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Venous thromboembolism **Important identified risk**	
Risk minimisation measures	Routine risk minimisation measures:

	SmPC sections "4.1 Therapeutic indications", "4.4 Special warnings and precautions for use", "4.6 Fertility, pregnancy and lactation" and "4.8 Undesirable effects". Pil sections "2 2. What you need to know before you take Estradiol valerate/dienogest " and "4 Possible side effects" Contraindication in SmPC section "4.3 Contraindications" Warning in case of appearance of conditions or risk factors, and recommendations for the early detection of thromboembolism is included "4.4 Special warnings and precautions for use" How to detect early signs and symptoms of thromboembolism is included in PL, section 2. - Prescription only medicine. Pil sections "2 2. What you need to know before you take Estradiol valerate/dienogest " and "4 Possible side effects <u>Additional risk minimisation measures:</u> Checklist for prescribers Patient information card

<u>Arterial thromboembolism</u> **Important identified risk**	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC sections "4.4 Special warnings and precautions for use" and "4.8 Undesirable effects". Pil sections "2 2. What you need to know before you take Estradiol valerate/dienogest " and "4 Possible side effects Contraindication in SmPC section "4.3 Contraindications" Warning in case of appearance of conditions or risk factors, and recommendations for the early detection of thromboembolism is included "4.4 Special warnings and precautions for use How to detect early signs and symptoms of thromboembolism is included in PL, section 2. - Prescription only medicine.

	Additional risk minimisation measures: Checklist for prescribers Patient information card

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 Qlady.

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

There are no studies required for Qlady.