

13 Part VI: Summary of the risk management plan for Levonorgestrel/ Ethinylestradiol, 100 µg/20 µg, 125 µg/30 µg and 150 µg/30 µg, Film-coated tablets

This is a summary of the risk management plan (RMP) for levonorgestrel/ ethinylestradiol, 100 µg/20 µg, 125 µg/30 µg and 150 µg/30 µg, film-coated tablets. The RMP details important risks of levonorgestrel/ ethinylestradiol, film-coated tablets, how these risks can be minimized, and how more information will be obtained about levonorgestrel/ ethinylestradiol, film-coated tablets' risks and uncertainties (missing information).

Levonorgestrel/ ethinylestradiol, film-coated tablets' summary of product characteristics (SmPCs) and its package leaflets give essential information to healthcare professionals and patients on how levonorgestrel/ ethinylestradiol, film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of the levonorgestrel/ ethinylestradiol, film-coated tablets' RMP.

13.1 Part VI: I. The medicine and what it is used for

Levonorgestrel/ ethinylestradiol, film-coated tablets are authorized for:

Oral contraception.

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

It contains levonorgestrel and ethinylestradiol as active substances and is given orally as film-coated tablets (100 µg/20 µg, 125 µg/30 µg and 150 µg/30 µg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of levonorgestrel/ ethinylestradiol, film-coated tablets, together with measures to minimize such risks and the proposed studies for learning more about levonorgestrel/ ethinylestradiol, film-coated tablets 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*.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of levonorgestrel/ ethinylestradiol, film-coated tablets 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 levonorgestrel/ ethinylestradiol, film-coated 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	VTE
	Arterial thromboembolism (ATE) (including cardiovascular disease and stroke)
Important potential risks	None
Missing information	None

13.2.2 Part VI – II.B: Summary of important risks

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

Table 13-2 Important identified risk: VTE

Risk minimization measures	<p>Routine risk minimization measures:</p> <p>SmPC sections 4.3, 4.4 where recommendations are given that in case of suspected or confirmed VTE with the use of levonorgestrel/ethinylestradiol, it should be discontinued and immediate medical attention should be taken.</p> <p>PL sections 2 where recommendations are given to the women patients to contact their doctor immediately in case they notice any of the signs and symptoms related to the risk of VTE.</p> <p>Legal status: Prescription only</p> <p>Additional risk minimization measures</p> <p>Checklist for Prescribers and Patient information card</p>
----------------------------	--

Table 13-3 Important identified risk: ATE (including cardiovascular disease and stroke)

Risk minimization measures	Routine risk minimization measures:
----------------------------	-------------------------------------

SmPC sections 4.3, 4.4 where recommendations are given that in case of suspected or confirmed ATE (including cardiovascular disease and stroke) with the use of levonorgestrel/ethinylestradiol, it should be discontinued and immediate medical attention should be taken.

PL sections 2 where advice is given to patients to seek medical attention immediately if they notice any signs and symptoms related to the risk of ATE (including cardiovascular disease and stroke).

Legal status: Prescription only

Additional risk minimization measures
Checklist for Prescribers and Patient information card

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 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 for levonorgestrel/ ethinylestradiol, film-coated tablets.

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

There are no studies required for levonorgestrel/ ethinylestradiol, film-coated tablets.