Summary of risk management plan for Norgestimate/Etinilestradiolo VI.REL Pharma

This is a summary of the risk management plan (RMP) for Norgestimate/Etinilestradiolo VI.REL Pharma. The RMP details important risks of Norgestimate/Etinilestradiolo VI.REL Pharma, how these risks can be minimised, and how more information will be obtained about Norgestimate/Etinilestradiolo VI.REL Pharma's risks and uncertainties (missing information).

Norgestimate/Etinilestradiolo VI.REL Pharma summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Norgestimate/Etinilestradiolo VI.REL Pharma should be used.

I. The medicine and what it is used for

Norgestimate/Etinilestradiolo VI.REL Pharma is authorised for female contraception (see SmPC for the full indication). It contains norgestimate/ethinylestradiol as the active substances 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 Norgestimate/Etinilestradiolo VI.REL Pharma, together with measures to minimise such risks and the proposed studies for learning more about Norgestimate/Etinilestradiolo VI.REL Pharma'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;
- 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 Norgestimate/Etinilestradiolo VI.REL Pharma, 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, including PSUR assessment, 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 Norgestimate/Etinilestradiolo VI.REL Pharma 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 Norgestimate/Etinilestradiolo VI.REL Pharma.

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	Venous thromboembolism (VTE) Arterial thromboembolism (ATE) Ovarian Cancer Gallbladder disorders
Important potential risks	Breast cancer Cervical cancer Pancreatitis Malignant liver tumours Worsening of Crohn's disease and ulcerative colitis Angioedema Insulin resistance/decreased glucose tolerance Depression Suicidal thoughts Drug interactions with hepatic enzyme inducers
Missing information	None

II.B Summary of important risks

Important identified risks:

Venous thromboembolism	
Risk minimisation measures	**Routine risk minimisation measures:** SmPC sections 4.1, 4.3; 4.4 and 4.8. PL section 2 and 4 Legal status: Prescription only medicine **Additional risk minimisation measures[1]:** • A direct healthcare professional communication (DHPC) • A checklist and educational material for prescribers • A "patient information card". This sheet provides the important signs and symptoms of VTE and ATE for women to be aware of thromboembolic events

Arterial thromboembolism	
Risk minimisation measures	**Routine risk minimisation measures:** SmPC sections 4.3; 4.4 and 4.8. PL section 2 and 4 Legal status: Prescription only medicine **Additional risk minimisation measures[1]:** • A direct healthcare professional communication (DHPC) • A checklist for prescribers. • And a "patient information card" in boxes was implemented. This sheet provides the important signs and symptoms of VTE and ATE for women to be aware of thromboembolic events.

[1] These three educational materials need to be discussed and possibly harmonised with NCAs, after approval.

Ovarian cancer	
Risk minimisation measures	**Routine risk minimisation measures:** SmPC section 4.3. PL section 2 and 4 Legal status: Prescription only medicine **Additional risk minimisation measures:** None

Gallbladder disorders	
Risk minimisation measures	**Routine risk minimisation measures:** SmPC section 4.4. PL section 2 and 4 Legal status: Prescription only medicine **Additional risk minimisation measures:** None

Important potential risks:

The safety information in the proposed Product Information is aligned to the reference medicinal product and other same generic products.

Missing information:

None.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation of Norgestimate/Etinilestradiolo VI.REL Pharma.

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

Not applicable