PART VI- Summary of the risk management plan forNorgestimate / Ethinylestradiol

The content of this part is the same for all invented names of norgestimate / ethinylestradiol tablets covered by this RMP.

This is a summary of risk management plan for *TriBriladona* (norgestimate/ ethinylestradiol 0.180mg/0.035mg + 0.215mg/0.035mg + 0.250mg/0.035mg tablet). The RMP details important risks of norgestimate/ ethinylestradiol tablets, how these risks can be minimised, and how more information will be obtained about norgestimate/ ethinylestradiol risks and uncertainties (missing information).

Norgestimate / ethinylestradiol tablet SmPC and PL give essential information to healthcare professionals and patients on how norgestimate/ ethinylestradiol should be used.

Important new concerns or changes to the current ones will be included in updates of the RMP of *TriBriladona.*

I. The medicine and what it is used for

TriBriladona is authorised for oral contraception for women with mild to moderate acne; this contraceptive treatment does not provide specific treatment for acne if it is necessary.

It contains norgestimate / ethinylestradiol as active substance 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 / ethinylestradiol tablet, together with measures to minimise such risks are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information in the PL and SmPC, such as warnings, precautions, and advice on correct use, which are 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 can be accessed by 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 / ethinylestradiol tablets, the routine risk minimisation measures are supplemented with additional risk minimization measures mentioned under relevant important risks, below.

Besides these measures, information about adverse reactions is continuously collected 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 norgestimate / ethinylestradiol tablets are those needing special management activities to further investigate or minimise the risk, so the 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 / ethinylestradiol 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).

List of important risks and missing information	
Important identified risks	- Venous thromboembolism - Arterial thromboembolism
Important potential risks	None
Missing information	None

II.B Summary of important risks

There are additional risk minimisation measures for the following important identified risks

Important identified risk Venous thromboembolism

Risk minimisation measures	**Routine risk minimisations measures:** SmPC sections 4.1, 4.4, 4.6 and 4.8 PL section 4 Contraindication in section 4.3 of the SmPC Warning in case of appearance of conditions or risk factors, and recommendations for the early detection of thromboembolism is included in section 4.4 of SmPC. How to detect early signs and symptoms of thromboembolism is included in PL, sections 2 and 3. Prescription Only Medicine. **Additional risk minimisation measures:** Checklist for prescribers. Patient information card.

Important identified risk Arterial thromboembolism	
Risk minimisation measures	**Routine risk minimisations measures:** SmPC sections 4.1, 4.4, 4.6 and 4.8 PL section 4 Contraindication in section 4.3 of the SmPC Warning in case of appearance of conditions or risk factors, and recommendations for the early detection of thromboembolism is included in section 4.4 of SmPC. How to detect early signs and symptoms of thromboembolism is included in PL, sections 2 and 3. 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 norgestimate / ethinylestradiol tablet.

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

There are no studies required for norgestimate / ethinylestradiol tablet.