

Summary of risk management plan for Vagiprev 0.120/0.015 mg Vaginal delivery system (etonogestrel/ethinylestradiol) Orion Corporation

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This is a summary of risk management plan (RMP) for Vagiprev 0.120/0.015 mg Vaginal delivery system. The RMP details important risks of Vagiprev 0.120/0.015 mg Vaginal delivery system, how these risks can be minimised, and how more information will be obtained about Vagiprev 0.120/0.015 mg Vaginal delivery system's risks and uncertainties (missing information).

Vagiprev 0.120/0.015 mg Vaginal delivery system's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Vagiprev 0.120/0.015 mg Vaginal delivery system should be used.

Important new concerns or changes to the current ones will be included in updates of Vagiprev 0.120/0.015 mg Vaginal delivery system's RMP.

I. The medicine and what it is used for

Vagiprev 0.120/0.015 mg Vaginal delivery system is authorised for contraception.

It contains etonogestrel and ethinylestradiol as active substances, and it is given by vaginal delivery system.

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

Important risks of Vagiprev 0.120/0.015 mg Vaginal delivery system, together with measures to minimise such 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 Vagiprev 0.120/0.015 mg Vaginal delivery system, these measures are supplemented with additional *risk minimisation measures* mentioned under relevant important risk, 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 Vagiprev 0.120/0.015 mg Vaginal delivery system 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 Vagiprev 0.120/0.015 mg Vaginal delivery system. 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	<ul style="list-style-type: none"> • Venous thromboembolism • Arterial thromboembolism
Important potential risks	<ul style="list-style-type: none"> • None
Missing information	<ul style="list-style-type: none"> • None

II.B Summary of important risks

Important identified risk: Venous thromboembolism	
Risk minimisation measures	Routine risk minimisation measures: <i>SmPC section 4.1, 4.3, 4.4, 4.6 and 4.8</i> <i>PL section 4</i> Additional risk minimisation measures: <i>Educational material for prescribers and patients</i>

Important identified risk: Arterial thromboembolism	
Risk minimisation measures	Routine risk minimisation measures: <i>SmPC section 4.3, 4.4 and 4.8</i> <i>PL section 4</i> Additional risk minimisation measures: <i>Educational material for prescribers and patients</i>

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Vagiprev 0.120/0.015 mg Vaginal delivery system

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

There are no studies required for Vagiprev 0.120/0.015 mg Vaginal delivery system.