

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR UTROGESTAN BESINS 300 mg SOFT CAPSULES (UTROGESTAN CAPSULES) (PROGESTERONE)

This is a summary of the risk management plan (RMP) for UTROGESTAN 300 mg Vaginal (Soft) Capsules.

The RMP details important risks of UTROGESTAN 300 mg Vaginal (Soft) Capsules, how these risks can be minimised, and how more information will be obtained about UTROGESTAN 300 mg Vaginal (Soft) Capsules' risks and uncertainties (missing information).

UTROGESTAN 300 mg Vaginal (Soft) Capsules' Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how UTROGESTAN 300 mg Vaginal (Soft) Capsules should be used.

I The medicine and what it is used for

UTROGESTAN 300 mg Vaginal (Soft) Capsules is authorised for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles. It contains Progesterone as the active substance and it is given for vaginal administration.

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

Important risks of UTROGESTAN 300 mg Vaginal (Soft) Capsules, together with measures to minimise such risks and the proposed studies for learning more about UTROGESTAN 300 mg Vaginal (Soft) Capsules' 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 types of measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures are called *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of UTROGESTAN 300 mg Vaginal (Soft) Capsules 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 enough proof of a link with the use of UTROGESTAN 300 mg Vaginal (Soft) Capsules. Potential risks are concerns for which an association with the use of these medicines 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	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

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

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 UTROGESTAN 300 mg Vaginal (Soft) Capsules.

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

There are no studies required for UTROGESTAN 300 mg Vaginal (Soft) Capsules.