PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

UTROGESTAN

Vaginal 200 mg Capsules

This is a summary of the risk management plan (RMP) for UTROGESTAN Vaginal 200 mg, Soft Capsules. The RMP provides details on the important risks, how these risks can be minimised, and whether more information will be obtained about the products' risks and any uncertainties (missing information).

The summary of product characteristics (SmPC) and package leaflet for UTROGESTAN Vaginal capsules give essential information to healthcare professionals and patients on how the product should be used.

Important new concerns or changes to the current concerns will be included in updates of the RMP for UTROGESTAN Vaginal 200 mg Soft Capsules.

I. The medicine and what it is used for

UTROGESTAN Vaginal Soft Capsules might be given to women who are undergoing fertility treatments such as *in vitro* fertilisation (IVF) to help them to get pregnant; or who have other fertility problems which need luteal phase support with progesterone, such as when a woman cannot produce an egg (please see the SmPC for the full indications). The product contains the natural hormone progesterone as the active substance and it is given by placing a capsule deep in the vagina.

Please see the SmPC for the full indications. The product contains the natural hormone progesterone as the active substance and it is given as a vaginal capsule.

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

Important risks of UTROGESTAN Vaginal Capsules and the measures to minimise these risks are outlined below in Sections II.A and II.B.

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

- 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 given on the packaging;
- The approved pack size - the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The legal status - the way a medicine is supplied to the public (e.g. with or without prescription) can help to minimise its risks.

Together, these types of measures are called *routine risk minimisation* measures.

In addition to these measures, information about adverse events (unwanted side effects) 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' are risks that need special management activities to further investigate or minimise the risk, so that the medicine can be safely taken.

Important risks can be classified as 'Identified' or 'Potential':

- Identified risks are concerns for which there is enough proof of a link with the use of UTROGESTAN Vaginal 100 mg, 200 mg, 300 mg and 400 mg Soft Capsules.
- Potential risks are concerns where a link with the use of these medicines is possible, but has not been fully proven and needs further assessment.

A third category is 'Missing Information' which refers to information on the safety of the medicine that is currently missing and needs to be collected (e.g. effects during long term use).

The safety profile of progesterone is well established. There are no additional safety concerns specific to the use of UTROGESTAN Vaginal 100 mg, 200 mg, 300 mg and 400 mg Soft Capsules.

II.B Summary of important risks

The safety profile of progesterone is well established. There are no additional safety concerns specific to the use of UTROGESTAN Vaginal 100 mg, 200 mg, 300 mg and 400 mg Soft Capsules and Oral 100 mg and 200 mg Capsules.

II.C Summary of missing information

There are no areas of information on the safety of the medicine that are currently missing and need to be collected.

II.D Post-authorisation development plan

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

Not applicable

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

Not applicable