PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR UTROGESTAN

Vaginal 100 / 200 / 300 / 400 mg Soft Capsules and Oral 100 / 200 mg Soft Capsules

This is a summary of the risk management plan (RMP) for UTROGESTAN Vaginal 100 mg, 200 mg, 300 mg and 400 mg Soft Capsules and Oral 100 mg and 200 mg Capsules. The RMP details important risks of UTROGESTAN Vaginal 100 mg, 200 mg, 300 mg and 400 mg Soft Capsules and Oral 100 mg and 200 mg Capsules, how these risks can be minimised, and whether more information will be obtained about the risks and uncertainties (missing information).

UTROGESTAN Vaginal 100 mg, 200 mg, 300 mg and 400 mg Soft Capsules and Oral 100 mg and 200 mg Capsules' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how UTROGESTAN Vaginal 100 mg, 200 mg, 300 mg and 400 mg Soft Capsules and Oral 100 mg and 200 mg Capsules should be used.

Important new concerns or changes to the current ones will be included in updates of UTROGESTAN Vaginal 100 mg, 200 mg, 300 mg and 400 mg Soft Capsules and Oral 100 mg and 200 mg Capsules.

I. The medicine and what it is used for

Oral

UTROGESTAN Oral 100 mg and 200 mg Soft Capsules is authorised for a number of uses;

- For women who are having problems with their menstrual periods
- For women who have non-cancerous breast lumps
- For women who have fertility problems which need luteal phase support with progesterone, to help prevent early delivery, or when there is a risk of losing the baby.
- this medicine can be used together with another medicine called oestrogen for women who have been through or who are about to go through the menopause, and who still have a womb. This is called Hormone Replacement Therapy (HRT).

Vaginal

UTROGESTAN Vaginal 100 mg, 200 mg, 300 mg and 400 mg Soft Capsules is authorised for 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 intra-vaginally.

Both oral and vaginal

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 or oral capsule.

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

Important risks of UTROGESTAN Vaginal 100 mg, 200 mg, 300 mg and 400 mg Soft Capsules and Oral 100 mg and 200 mg Soft Capsules, together with measures to minimise such risks are outlined below in Sections II.A and II.B.

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 approved 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 minimises 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 Vaginal 100 mg, 200 mg, 300 mg and 400 mg Soft Capsules and Oral 100 mg and 200 mg Soft Capsules are risks that need special risk management activities to further investigate or minimise the risk, so that the medicine 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 Vaginal 100 mg, 200 mg, 300 mg and 400 mg Capsules and Oral 100 mg and 200 mg 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).

The safety profile of progesterone is very 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 Soft Capsules.

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

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.C Post-authorisation development plan

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

Not applicable

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

Not applicable