Summary of risk management plan for Menovag 10 micrograms vaginal tablets (estradiol hemihydrate) Orion Corporation

Date: 01-10-2019, Version 1.1

This is a summary of the risk management plan (RMP) for Menovag. The RMP details important risks of Menovag, how these risks can be minimised, and how more information will be obtained about Menovag's risks and uncertainties (missing information).

Menovag's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Menovag should be used.

Important new concerns or changes to the current ones will be included in updates of Menovag's RMP.

I. The medicine and what it is used for

Menovag is authorised for treatment of vaginal atrophy due to oestrogen deficiency in postmenopausal women. It contains estradiol as the active substance and it is administered intravaginally.

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

Important risks of Menovag, together with measures to minimise such risks and the proposed studies for learning more about Menovag's 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 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*.

If important information that may affect the safe use of Menovag is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.

Safety concerns are adequately addressed in the product information.

II.B Summary of important risks

Safety concerns are adequately addressed in the product information.

II.C Post-authorisation development plan

There are no studies required for Menovag.