Part VI: Summary of the risk management plan

Summary of risk management plan for EU Risk Management Plan for Fulvestrant STADA 250 mg Injektionslösung in einer Fertigspritze (Fulvestrant)

This is a summary of the risk management plan (RMP) for Fulvestrant STADA 250 mg. The RMP details important risks of Fulvestrant STADA 250 mg, how these risks can be minimised, and how more information will be obtained about Fulvestrant STADA 250 mg's risks and uncertainties (missing information).

Fulvestrant STADA 250 mg's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Fulvestrant STADA 250 mg should be used.

I. The medicine and what it is used for

Fulvestrant STADA 250 mg is authorised for the treatment of oestrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women and in combination with palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer (see SmPC for the full indication). It contains Fulvestrant as the active substance and it should be administered as two consecutive 5 ml injections.

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

Important risks of Fulvestrant STADA 250 mg, together with measures to minimise such risks and the proposed studies for learning more about Fulvestrant STADA 250 mg'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.

II.A List of important risks and missing information

Important risks of Fulvestrant STADA 250 mg are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Fulvestrant STADA 250 mg. 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	• 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 Fulvestrant STADA 250 mg.

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

There are no studies required for Fulvestrant STADA 250 mg.