Part VI: Summary of the risk management plan

Summary of risk management plan for Fulvestrant Accord 250 mg solution for injection in pre-filled syringe (Fulvestrant)

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

Fulvestrant Accord 250 mg solution for injection in pre-filled syringe's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Fulvestrant Accord 250 mg solution for injection in pre-filled syringe should be used.

Important new concerns or changes to the current ones will be included in updates of Fulvestrant Accord 250 mg solution for injection in pre-filled syringe's RMP.

I. The medicine and what it is used for

Fulvestrant Accord is indicated

- as monotherapy for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women:

  - not previously treated with endocrine therapy, or

  - with disease relapse on or after adjuvant antiestrogen therapy, or disease progression on antiestrogen therapy.

- 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 in women who have received prior endocrine therapy.

In pre- or perimenopausal women, the combination treatment with palbociclib should be combined with a luteinizing hormone releasing hormone (LHRH) agonist.

It contains fulvestrant as the active substance and it is given by intramuscular route.

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

Important risks of Fulvestrant Accord 250 mg solution for injection in pre-filled syringe, together with measures to minimise such risks and the proposed studies for learning more about Fulvestrant Accord 250 mg solution for injection in pre-filled syringe'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, including signal management activity, 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 Fulvestrant Accord 250 mg solution for injection in pre-filled syringe is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Fulvestrant Accord 250 mg solution for injection in pre-filled syringe 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 Accord 250 mg solution for injection in pre-filled syringe. 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).

Safety concerns	
Important identified risks	• Injection site reactions • Increased risk of bleeding at the injection site • Hypersensitivity reactions • Venous thromboembolic events • Hepatobiliary disorders
Important potential risks	• Reduced bone mineral density (osteopenia) and osteoporosis • Ischaemic cardiovascular events • Endometrial dysplasia • Interstitial lung disease • Vasculitis • Pulmonary microembolism of oily solutions • Reprotoxicity (fertility, pregnancy and lactation)
Missing information	• Paediatric use • Use with severe hepatic impairment • Use with severe renal impairment

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 Accord 250 mg solution for injection in pre-filled syringe.

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

There are no studies required for Fulvestrant Accord 250 mg solution for injection in pre-filled syringe.