13 Part VI: Summary of the risk management plan for Femara®

This is a summary of the risk management plan (RMP) for Femara. Currently there are no important identified, potential risks, and missing information for Femara.

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

13.1 Part VI: I. The medicine and what it is used for

Femara is indicated for the treatment of breast cancer in women who have gone through menopause (see SmPC for the full indication).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Measures to minimize the risks identified for Femara 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 authorized 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 minimize its risks.

Together, these measures constitute routine risk minimization measures. In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken. 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 Femara. 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).With this update, there are no important risks or missing information for the Femara.

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

13.2.2 Part VI - II B: Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

13.2.3 Part VI – II C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Femara.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for Femara.