Part VI: Summary of the risk management plan

Summary of risk management plan for Letrozole 2.5 mg film coated tablets (letrozole)

This is a summary of the risk management plan (RMP) for Letrozole 2.5 mg film coated tablets. The RMP details important risks of letrozole 2.5 mg film coated tablets, how these risks can be minimized, and how more information will be obtained about letrozole 2.5 mg film coated tablets' risks and uncertainties (missing information).

Letrozole 2.5 mg film coated tablets' summary of product characteristics (SmPCs) and its package leaflets (PLs) give essential information to healthcare professionals (HCPs) and patients on how letrozole 2.5 mg film coated tablet should be used.

Important new concerns or changes to the current ones will be included in updates of the letrozole 2.5 mg film coated tablets' RMP.

I. The medicine and what it is used for

Letrozole 2.5 mg film coated tablets is authorized for:

- Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer.
- Extended adjuvant treatment of hormone-dependent-invasive breast cancer in postmenopausal women who have received prior standard adjuvant tamoxifen therapy for 5 years.
- First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer.
- Advanced breast cancer after relapse or disease progression, in women with natural or artificially induced postmenopausal endocrine status, who have previously been treated with anti-oestrogens.
- Neo-adjuvant treatment of postmenopausal women with hormone receptor positive, HER-2 negative breast cancer where chemotherapy is not suitable and immediate surgery not indicated. (see SmPC for the full indication).

It contains letrozole as an active substance and it is taken orally as film coated tablets.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of letrozole 2.5 mg film coated tablets, together with measures to minimize such risks and the proposed studies for learning more about letrozole 2.5 mg film coated tablets' risks, are outlined below.

Measures to minimize 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 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 analyzed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of letrozole 2.5 mg film coated tablets 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 letrozole 2.5 mg film coated tablets. 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

Not applicable.

II.C Post-authorization development plan

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 letrozole 2.5 mg film coated tablets.

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

There are no studies required for letrozole 2.5 mg film coated tablets.