13 Part VI: Summary of the risk management plan for Anastrozole*, 1 mg, Film-coated tablet

***RMS-AT**

AT/H/0990
Anastrozol 1A Pharma 1 mg–Filmtabletten

AT/H/0882
Anastrozol Sandoz 1 mg–Filmtabletten

RMS-DE
DE/H/5647
AnastroHEXAL 1 mg Filmtabletten

DE/H/5648
Anastrozol-1 A Pharma 1 mg Filmtabletten

DE/H/5648
Anastrozol-1 A Pharma 1 mg Filmtabletten

National Procedure (NP) – HR
Anastrozol Sandoz 1 mg filmom obložene tablete

RMS-NL
NL/H/0841
Anastrozol Sandoz 1 mg, Filmomhulde Tabletten

This is a summary of the risk management plan (RMP) for anastrozole, 1 mg, film-coated tablet. The RMP details important risks of anastrozole, film-coated tablet, how these risks can be minimized, and how more information will be obtained about anastrozole, film-coated tablet's risks and uncertainties (missing information).

Anastrozole, film-coated tablet's summary of product characteristics (SmPCs) and its package leaflets (PLs) gives essential information to healthcare professionals (HCPs) and patients on how anastrozole, film-coated tablet should be used.

Important new concerns or changes to the current ones will be included in updates of the anastrozole, film-coated tablet's RMP.

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

Anastrozole, film-coated tablet is authorized for:

- Treatment of hormone receptor-positive advanced breast cancer in postmenopausal women.
- Adjuvant treatment of hormone receptor-positive early invasive breast cancer in postmenopausal women.
- Adjuvant treatment of hormone receptor-positive early invasive breast cancer in postmenopausal women who have received 2 to 3 years of adjuvant tamoxifen.

It contains anastrozole as an active substance and is taken orally as film-coated tablet (1 mg).

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

Important risks of anastrozole, film-coated tablet, together with measures to minimize such risks and the proposed studies for learning more about anastrozole, film-coated tablet's risks are outlined below.

Measures to minimize the risk identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PLs and SmPCs addressed to patients and HCPs;

- 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*.

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

Important risks of anastrozole, film-coated tablet 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 anastrozole, film-coated tablet. 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	None
Important potential risks	Rheumatoid arthritis
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 anastrozole, film-coated tablet.

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

There are no studies required for anastrozole, film-coated tablet.