

**Part VI: Summary of the risk management plan**

Summary of risk management plan for Anastrozole.

This is a summary of the risk management plan (RMP) for Anastrozole. The RMP details important risks of Anastrozole, risk minimisation measures needed to minimise these risks and routine pharmacovigilance activities needed to obtain more information about Anastrozole risks and uncertainties (missing information).

Anastrozole summary of product characteristics gives essential information to healthcare professionals and patients on how Anastrozole should be used.

Important new concerns or changes to the current ones will be included in updates of Anastrozole's RMP.

**I. The medicine and what it is used for**

Anastrozole is indicated for the:

- 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 the active substance and it is given orally.

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

Important risks of Anastrozole, together with measures to minimise such risks and learning more about Anastrozole 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 leaflets and SmPCs 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, 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 Anastrozole 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 Anastrozole. 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.

Important identified risks	None
Important potential risks	None
Missing information	None

**II.B Summary of important risks**

The safety information in the proposed summary of product characteristics (SmPC), labelling and package information leaflet (PIL) is aligned to the reference medicinal product.

**II.C Post-authorisation development plan**

No post authorisation study is planned for this product.

**II.C.1 Studies which are conditions of the marketing authorisation**

There are no studies which are conditions of the marketing authorisation or which are a specific obligation of Anastrozole.

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

There are no studies required for Anastrozole.

**Part VII: Annexes***Annex 1 – EudraVigilance Interface*

Not applicable.

*Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme*

Not applicable.

*Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan*

Not applicable.

*Annex 4 - Specific adverse drug reaction follow-up forms*

Not applicable.

*Annex 5 - Protocols for proposed and on-going studies in RMP part IV*

Not applicable.

*Annex 6 - Details of proposed additional risk minimisation activities (if applicable)*

Not applicable.

*Annex 7 - Other supporting data (including referenced material)*

Not applicable.

*Annex 8 – Summary of changes to the risk management plan over time*

Version	Approval date procedure	Change
1.1	National	As per the authority recommendation, RMP has been updated to include the QPPV information and to be inline with the GVP Module V, rev 2 template. Accordingly, Part I, II, VI and VII of RMP has been updated.
1.0	20-03-2020 National	Initial application