Part VI: Summary of the risk management plan

Summary of risk management plan for Enzalutamide Sandoz 40 mg, 80 mg, filmomhulde tabletten and Enzalutamide 1A Pharma 40 mg, 80 mg, filmomhulde tabletten (Enzalutamide)

This is a summary of the risk management plan (RMP) for enzalutamide. The RMP details important risks of Enzalutamide Sandoz 40 mg, 80 mg, filmomhulde tabletten and Enzalutamide 1A Pharma 40 mg, 80 mg, filmomhulde tabletten (Enzalutamide Sandoz / Enzalutamide 1A Pharma), how these risks can be minimised, and how more information will be obtained about enzalutamide's risks and uncertainties (missing information).

Enzalutamide Sandoz / Enzalutamide 1A Pharma's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Enzalutamide Sandoz / Enzalutamide 1A Pharma should be used.

Important new concerns or changes to the current ones will be included in updates of Enzalutamide Sandoz / Enzalutamide 1A Pharma RMP.

I. The medicine and what it is used for

Enzalutamide Sandoz / Enzalutamide 1A Pharma is indicated:

• as monotherapy or in combination with androgen deprivation therapy for the treatment of adult men with high-risk biochemical recurrent (BCR) non-metastatic hormone-sensitive prostate cancer (nmHSPC) who are unsuitable for salvage-radiotherapy.

• in combination with androgen deprivation therapy for the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC).

• for the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC).

• for the treatment of adult men with metastatic CRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.

• for the treatment of adult men with metastatic CRPC whose disease has progressed on or after docetaxel therapy.

It contains enzalutamide as the active substance, and it is given by oral route of administration of 40 mg and 80 mg film-coated tablets.

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

Important risks of Enzalutamide Sandoz / Enzalutamide 1A Pharma, together with measures to minimise such risks and the proposed studies for learning more about enzalutamide'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, 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 Enzalutamide Sandoz / Enzalutamide 1A Pharma 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 enzalutamide. 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	• Seizure • Fall • Non-pathological fracture • Ischemic heart disease
Important potential risks	None
Missing information	None

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 Enzalutamide Sandoz / Enzalutamide 1A Pharma.

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

There are no studies required for Enzalutamide Sandoz / Enzalutamide 1A Pharma.