13 Part VI: Summary of the risk management plan (RMP) – Enzalutamide, 40 mg and 80 mg, Film-coated tablets

This is a summary of the RMP for enzalutamide, 40 mg and 80 mg, film-coated tablets. The RMP details important risks of enzalutamide, film-coated tablets and how information will be obtained about enzalutamide, film-coated tablets' risks and uncertainties (missing information).

Enzalutamide, film-coated tablets' summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how enzalutamide, film-coated tablets should be used.

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

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

Enzalutamide is indicated for:

- The treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy.
- The treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC).
- 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.
- 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 taken orally as film-coated tablets (40 mg and 80 mg).

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

Important risks of enzalutamide, film-coated tablets, together with measures to minimize such 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 PL and SmPC 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, including Periodic Safety Update Reports (PSURs) assessment (if

applicable) 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 enzalutamide, 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 enzalutamide, 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).

Table 13-1 List of important risks and missing information

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

13.2.2 Part VI – II.B: Summary of important risks

The safety information in the proposed Product Information is aligned to the originator 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 enzalutamide, film-coated tablets.

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

There are no studies required for enzalutamide, film-coated tablets.