Part VI: Summary of the risk management plan

Summary of risk management plan for

Enzalutamide SUN and Enzalutamide SUN Pharma 40 mg, 80 mg, 160 mg – film-coated tablets

(enzalutamide)

This is a summary of the risk management plan (RMP) for Enzalutamide SUN and Enzalutamide SUN Pharma 40 mg, 80 mg, 160 mg – film-coated tablets. The RMP details important risks of Enzalutamide SUN and Enzalutamide SUN Pharma 40 mg, 80 mg, 160 mg – film-coated tablets, how these risks can be minimised, and how more information will be obtained about Enzalutamide SUN and Enzalutamide SUN Pharma 40 mg, 80 mg, 160 mg – film-coated tablets risks and uncertainties (missing information).

Enzalutamide SUN and Enzalutamide SUN Pharma 40 mg, 80 mg, 160 mg – film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Enzalutamide SUN and Enzalutamide SUN Pharma 40 mg, 80 mg, 160 mg – film-coated tablets should be used.

I. The medicine and what it is used for

Enzalutamide SUN and Enzalutamide SUN Pharma 40 mg, 80 mg, 160 mg – film-coated tablets is authorised for the treatment of adult men with high risk biochemical recurrent (BCR) non-metastatic hormone-sensitive prostate cancer (nmHSPC); for the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy; 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 and for the treatment of adult men with metastatic CRPC whose disease has progressed on or after docetaxel therapy (see SmPC for the full indication).

It contains enzalutamide as the active substance, and it is given orally as film-coated tablets 160 mg enzalutamide (four 40 mg film-coated tablets, two 80 mg film-coated tablets or one 160 mg film-coated tablet) as a single oral daily dose.

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

Important risks of enzalutamide, 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. prescription only medicine) 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, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Enzalutamide is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Enzalutamide SUN and Enzalutamide SUN Pharma 40 mg, 80 mg, 160 mg – film-coated tablets 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.

List of important risks and missing information	
Important identified risks	• Seizure • Fall • Non-pathological fracture • Ischaemic Heart Disease
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

The safety information in the proposed Product Information (SPC and PIL) of Enzalutamide SUN and Enzalutamide SUN Pharma 40 mg, 80 mg, 160 mg – film-coated tablets 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 SUN and Enzalutamide SUN Pharma 40 mg, 80 mg, 160 mg – film-coated tablets.

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

There are no studies required for Enzalutamide SUN and Enzalutamide SUN Pharma 40 mg, 80 mg, 160 mg – film-coated tablets.