Part VI: Summary of the risk management plan

Summary of risk management plan for Abiraterone 250 mg and 500 mg film-coated tablets (Abiraterone)

This is a summary of the risk management plan (RMP) for Abiraterone. The RMP details important risks of Abiraterone, how these risks can be minimised, and how more information will be obtained about Abiraterone risks and uncertainties (missing information).

Abiraterone´s Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Abiraterone should be used.

Important new concerns or changes to the current ones will be included in updates of this Abiraterone RMP.

I. The medicine and what it is used for

The tablets are indicated with prednisone or prednisolone for:

- the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT).
- the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.
- the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

The tablets contain abiraterone as the active substance and are given by oral route of administration.

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

Important risks of Abiraterone, together with measures to minimise such 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.

II.A List of important risks and missing information

Important risks of Abiraterone 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 Abiraterone. 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	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to that of 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 Abiraterone.

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

There are no studies required for Abiraterone.