13 Part VI: Summary of the risk management plan (RMP) – Abiraterone acetate, 250 mg, 500 mg and 1000 mg, Film-coated tablets

This is a summary of the RMP for abiraterone acetate, 250 mg, 500 mg and 1000 mg, film-coated tablets. The RMP details important risks of abiraterone acetate, film-coated tablets, how these risks can be minimized, and how more information will be obtained about abiraterone acetate, film-coated tablet's risks and uncertainties (missing information).

Abiraterone acetate, film-coated tablet's summaries of product characteristics (SmPCs) and its package leaflets (PLs) give essential information to healthcare professionals (HCPs) and patients on how abiraterone acetate, film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of the abiraterone acetate, film-coated tablet's RMP.

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

Abiraterone acetate is 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.

It contains abiraterone acetate as the active substance and is taken orally as film-coated tablets (250 mg, 500 mg and 1000 mg).

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

Important risks of abiraterone acetate, 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 PLs and SmPCs 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 Report (PSUR) assessment (if applicable) 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 abiraterone acetate, film-coated tablets is not yet available, it is listed under 'missing information' below.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of abiraterone acetate, 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 abiraterone acetate, 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	Hepatotoxicity
	Cardiac disorders
	Osteoporosis including osteoporosis-related fractures
	Rhabdomyolysis/myopathy
	Allergic alveolitis
	Increased exposure with food
Important potential risks	Anemia
	Cataract
	Drug-drug interaction (CYP2D6)
Missing information	Use in patients with active or symptomatic viral hepatitis
	Use in patients with moderate/severe hepatic impairment and chronic liver disease
	Use in patients with severe renal impairment
	Use in patients with heart disease as evidenced by myocardial infarction (MI), or arterial thrombotic events in the past 6 months, severe or unstable angina, or New York Heart Association Class III or IV heart disease or cardiac ejection fraction measurement of <50%

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

The safety information in the proposed Product Information is aligned to the reference medicinal 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 abiraterone acetate, film-coated tablets.

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

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