Summary of risk management plan for Abiraterone KRKA

This is a summary of the risk management plan (RMP) for Abiraterone KRKA. The RMP details important risks of Abiraterone KRKA, how these risks can be minimised, and how more information will be obtained about Abiraterone KRKA's risks and uncertainties (missing information).
Abiraterone KRKA's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Abiraterone KRKA should be used.
This summary of the RMP for Abiraterone KRKA should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).
Important new concerns or changes to the current ones will be included in updates of Abiraterone KRKA's RMP.

I. The medicine and what it is used for

Abiraterone KRKA is indicated with prednisone or prednisolone for treatment of prostate cancer (see SmPC for the full indication). It contains abiraterone acetate as the active substance and it is given orally.
Further information about the evaluation of Abiraterone KRKA's benefits can be found in Abiraterone KRKA's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/abiraterone-acetate-krka

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

Important risks of Abiraterone KRKA, together with measures to minimise such risks and the proposed studies for learning more about Abiraterone KRKA'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*.
If important information that may affect the safe use of Abiraterone KRKA is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Abiraterone KRKA are risks that need special risk management activities to further investigate or minimise 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 KRKA. 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);

Summary of safety concerns	
Important identified risks	Hepatotoxicity Cardiac disorders Osteoporosis including osteoporosis-related fractures Rhabdomyolysis/Myopathy Allergic alveolitis Increased exposure with food
Important potential risks	Anaemia 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, 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%

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 Abiraterone KRKA.

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

There are no studies required for Abiraterone KRKA.