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Summary of the Risk Management Plan (RMP) for Zytiga® (abiraterone acetate)

Marketing Authorisation Holder (MAH): Janssen-Cilag AG

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Disclaimer:

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Zytiga® is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Zytiga® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Janssen-Cilag AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Zytiga®.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for ZYTIGA (Abiraterone Acetate)

This is a summary of the risk management plan (RMP) for ZYTIGA. The risks associated with ZYTIGA are well characterized and managed with established routine risk minimization measures, therefore, there are no important risks or uncertainties (missing information) associated with this product.
ZYTIGA's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how ZYTIGA should be used.
This summary of the RMP for ZYTIGA 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 will be included in updates of ZYTIGA's RMP.

I. The Medicine and What it is Used For

ZYTIGA, with prednisone or prednisolone,is authorized for the following (see SmPC for the full indication):

- 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 ADT in whom chemotherapy is not yet clinically indicated.
- the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxelbased chemotherapy regimen.

ZYTIGA contains abiraterone acetate as the active substance and it is given by orally by tablet or film-coated tablet.
Further information about the evaluation ofZYTIGA’s benefits can be found inZYTIGA’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/zytiga.

II. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Not applicable, as there are no important identified risks or important potential risks for ZYTIGA.

II.A. List of Important Risks and Missing Information

There are no important identified risks, important potential risks, or missing information for ZYTIGA.

II.B. Summary of Important Risks

There are no important identified risks, important potential risks, or missing information for ZYTIGA.

II.C. Postauthorization Development Plan

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 ZYTIGA.

II.C.2. Other Studies in Postauthorization Development Plan

There are no studies required for ZYTIGA.