Janssen-Cilag AG
Gubelstrasse 34
CH-6300 Zug
tel +41 58 231 34 34
fax +41 58 231 34 00

Summary of the Risk Management Plan (RMP) for DACOGEN® (decitabine)

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 DACOGEN® 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 DACOGEN® 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 DACOGEN®.

Summary of Risk Management Plan for DACOGEN (decitabine)

This is a summary of the risk management plan (RMP) for DACOGEN. Over 12 years' market experience with DACOGEN has demonstrated a favorable benefit-risk profile for the indication specified in this RMP and, therefore, there are no important risks or uncertainties (missing information) associated with this product.

DACOGEN's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how DACOGEN should be used.

Important new concerns will be included in updates of DACOGEN's RMP.

I. The Medicine and What it is Used For

DACOGEN is authorized for acute myeloid leukemia (AML) (see SmPC for the full indication). It contains decitabine as the active substance and it is administered intravenously.

Further information about the evaluation of DACOGEN's benefits can be found in DACOGEN's European public assessment report (EPAR), including in its plain-language summary, available on the European Medicines Agency (EMA)website, under the medicine's webpage.

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 DACOGEN.

II.A. List of Important Risks and Missing Information

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

II.B. Summary of Important Risks

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

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 DACOGEN.

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

There are no studies required for DACOGEN.