SWISS SUMMARY OF THE RISK MANAGEMENT PLAN

for

Vyxeos liposomal

Active Substances: Daunorubicin / Cytarabine

Version 1.0, 15 March 2022
Based on Version 0.2 of the EU RMP, 11 October 2018

Marketing Authorisation Holder: Clinipace AG

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 Vyxeos liposomal 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 Vyxeos liposomal in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Clinipace AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Vyxeos liposomal.

SUMMARY OF RISK MANAGEMENT PLAN FOR VYXEOS LIPOSOMAL

I THE MEDICINE AND WHAT IT IS USED FOR

Vyxeos liposomal is authorised for the treatment of newly diagnosed adults with high-risk acute myeloid leukaemia (AML) as defined by therapy-related acute myeloid leukaemia (t-AML) or acute myeloid leukaemia with myelodysplasia-related changes (AML-MRC).

Further information about the evaluation of the benefits of Vyxeos liposomal can be found in the Vyxeos EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage link to:
http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/human/medicines/human_med_002273.jsp&mid=WC0b01ac058001d124

II RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of Vyxeos liposomal, 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Period Safety Update Report (PSUR) assessment - 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 Vyxeos liposomal is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Not applicable as there are no Important Identified Risks, Important Potential Risks and/or Missing Information for Vyxeos liposomal.

II.B Summary of Important Risks

Not applicable as there are no Important Identified Risks and/or Important Potential Risks for Vyxeos liposomal.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of Vyxeos liposomal.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Vyxeos liposomal.