Part VI: Summary of the risk management plan

Summary of risk management plan for
Azacitidine STADA 25 mg/ml powder for suspension for injection

This is a summary of the risk management plan (RMP) for Azacitidine STADA. The RMP details important risks of Azacitidine STADA, how these risks can be minimised, and how more information will be obtained about Azacitidine STADA's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Azacitidine STADA is authorised for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (HSCT) with: intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS), chronic myelomonocytic leukaemia (CMML) with 10-29 % marrow blasts without myeloproliferative disorder, acute myeloid leukaemia (AML) with 20-30 % blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) classification, AML with > 30 % marrow blasts according to the WHO classification (see SmPC for the full indication). It contains azacitidine as the active substance and it is given parenterally.

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

Important risks of Azacitidine STADA, together with measures to minimise such risks and the proposed studies for learning more about Azacitidine STADA'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.

II.A List of important risks and missing information

Important risks of Azacitidine STADA are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Azacitidine STADA. 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);

List of important risks and missing information	
Important identified risks	• Haemorrhagic events • Infections
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Haemorrhagic events **Important identified risk**	
Risk minimisation measures	Routine risk minimisation measures: *SmPC sections 4.2, 4.4 and 4.8* – Restricted medical prescription Additional risk minimisation measures: - *N/A*

Infections **Important identified risk**	
Risk minimisation measures	Routine risk minimisation measures: *SmPC sections 4.2, 4.4 and 4.8* – Restricted medical prescription Additional risk minimisation measures: - *N/A*

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 Azacitidine STADA.

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

There are no studies required for Azacitidine STADA.