Part VI: Summary of the risk management plan

Summary of risk management plan for or Azacitidine Betapharm (azacitidine)

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

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

Important new concerns or changes to the current ones will be included in updates of Azacitidine Betapharm's RMP.

I. The medicine and what it is used for

Azacitidine Betapharm is authorised for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (HSCT) with higher-risk myelodysplastic syndromes (MDS), chronic myelomonocytic leukaemia (CMML) or acute myeloid leukaemia (AML) (see SmPC for the full indication). It contains azacitidine as the active substance and it is given by subcutaneous administration.

Further information about the evaluation of Azacitidine Betapharm's benefits can be found in Azacitidine Betapharm'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/azacitidine-betapharm.

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

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

II.A List of important risks and missing information

Important risks of Azacitidine Betapharm 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 Betapharm. 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

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 Azacitidine Betapharm.

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

There are no studies required for Azacitidine Betapharm.