Souhrn plánu řízení rizik podle § 99 odst. 8 písm. a) zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů (1)

Azacitidine Rompharm 25 mg/ml prášek pro injekční suspenzi

Administrativní informace:

Léčivá látka/látky	azacitidin
Léková forma/formy	Prášek pro injekční suspenzi
Síla/síly	25 mg/mL
Držitel rozhodnutí o registraci	Rompharm Company S.R.L., Judet Ilfov
Registrační číslo/čísla	44/473/24-C
Verze a datum plánu řízení rizik	1.0

Následující výňatek z plánu řízení rizik (RMP) výše uvedeného léčivého přípravku/léčivých přípravků je souhrnem podstatných informací uvedených ve zmíněném RMP. RMP popisuje opatření, která mají být přijata, aby bylo zajištěno, že tento léčivý přípravek/tyto léčivé přípravky budou používány co nejbezpečněji. Souhrn RMP je potřeba číst spolu se schváleným souhrnem údajů o přípravku/přípravcích a příbalovou informací.

Tento souhrn RMP připravil Státní ústav pro kontrolu léčiv za účelem splnění své zákonné povinnosti týkající se transparentnosti vůči veřejnosti.

1) Zákon č. 378/2007 Sb., o léčivech, ve znění pozdějších předpisů

Summary of risk management plan for Azacitidine Rompharm 25 mg/ml powder for concentrate for solution for infusion (Azacitidine)

This is a summary of the risk management plan (RMP) for *Azacitidine Rompharm 25 mg/mL powder for suspension for injection*. The RMP details important risks of *Azacitidine Rompharm 25 mg/mL powder for suspension for injection*, how these risks can be minimised, and how more information will be obtained about *Azacitidine Rompharm 25 mg/mL powder for suspension for injection* 's risks and uncertainties (missing information).

Azacitidine Rompharm 25 mg/mL powder for suspension for injection's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how *Azacitidine Rompharm 25 mg/mL powder for suspension for injection* should be used.

Important new concerns or changes to the current ones will be included in updates of *Azacitidine Rompharm 25 mg/mL powder for suspension for injection*'s RMP.

I. The medicine and what it is used for

Azacitidine Rompharm is indicated 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.

It contains azacitidine as the active substance and it is given subcutaneously.

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

Important risks of *Azacitidine Rompharm 25 mg/mL powder for suspension for injection*, together with measures to minimise such risks and the proposed studies for learning more about *Azacitidine Rompharm 25 mg/mL powder for suspension for injection* '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 Rompharm 25 mg/mL powder for suspension for injection* 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 Rompharm 25 mg/mL powder for suspension for injection*. 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

Summary of safety concerns	
Important identified risks	Haemorrhagic events (Bleeding related problems) 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 authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of *Azacitidine Rompharm 25 mg/mL powder for suspension for injection.*

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

There are no on-going or closed studies for *Azacitidine Rompharm 25 mg/mL powder for suspension for injection.*