Summary of the risk management plan

Summary of risk management plan for Voraxaze (Glucarpidase)

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

Voraxaze's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Voraxaze should be used.

This summary of the RMP for Voraxaze should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Voraxaze is indicated to reduce toxic plasma methotrexate concentration in adults and children (aged 28 days and older) with delayed methotrexate elimination or at risk of methotrexate toxicity. It contains glucarpidase as the active substance and it is given by the intravenous (IV) route of administration.

Further information about the evaluation of Voraxaze's benefits can be found in Voraxaze's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage. https://www.ema.europa.eu/en/medicines/human/EPAR/voraxaze-0

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

Important risks of Voraxaze, together with measures to minimise such risks and the proposed studies for learning more about Voraxaze'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, including Periodic Safety Update Report (PSUR) assessment 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 Voraxaze 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 Voraxaze. 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	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

There are no important risks associated with Voraxaze use.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

The following study is a condition of the Marketing Authorisation:

Voraxaze patient registry study: To obtain safety and efficacy data for Voraxaze in patients with impaired MTX clearance.

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

There are no studies required for Voraxaze.