Summary of Risk Management Plan for Deferasirox Mylan film-coated tablets (Deferasirox)

This is a summary of the risk management plan (RMP) for Deferasirox Mylan film-coated tablets. The RMP details important risks of deferasirox, how these risks can be minimised, and how more information will be obtained about deferasirox's risks and uncertainties (missing information).

Deferasirox Mylan film-coated tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

This summary of the RMP for Deferasirox Mylan film-coated tablets should be read in the context of all the 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 Deferasirox Mylan film-coated tablet's RMP.

I. The Medicine and What it is Used For

Deferasirox is indicated for:

Deferasirox Mylan film-coated tablets is authorised for the treatment of chronic iron overload due to frequent blood transfusions (≥7 ml/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older.

Deferasirox Mylan film-coated tablets is also indicated for the treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate.

Deferasirox Mylan film-coated tablets is also indicated for the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older.

It contains deferasirox as the active substance and it is given by oral route of administration.

Further information about the evaluation of Deferasirox Mylan film-coated tablets' benefits can be found in Deferasirox Mylan film-coated tablets 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/deferasirox-mylan.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Deferasirox Mylan film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Deferasirox Mylan film-coated tablets' 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including 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 Deferasirox Mylan film-coated tablets is not yet available, it is listed under 'missing information' below.

In the case of Deferasirox Mylan film-coated tablets, these routine measures are supplemented with additional risk minimisation measures, mentioned under relevant risks below.

II.A List of Important Risks and Missing Information

Important risks of Deferasirox Mylan film-coated tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 Deferasirox Mylan film-coated tablets. 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/use in special patient populations, etc.).

Table: Summary of safety concerns

List of Important Risks and Missing Information	
Important Identified Risks	• Renal disorders (increased serum creatinine, acute renal failure, renal tubular disorders (acquired Fanconi's syndrome)) (Kidney disorders) • Increased liver transaminases (Increased liver enzymes)/ Hepatic failure (Liver failure) • Gastrointestinal hemorrhage and ulcers; esophagitis • Hearing loss • Lens opacities, retinal changes and optic neuritis (Eye disorders: retinal changes and inflammation of the optic nerve)
Important Potential Risks	• Compliance with posology and biological monitoring

	• Medication errors
Missing Information	• Long term safety in paediatric NTDT patients aged 10 to 17 years

II.B Summary of Important Risks

Table: Important Identified Risk: Renal disorders (increased serum creatinine, acute renal failure, renal tubular disorders (acquired Fanconi's syndrome)) (Kidney disorders)

Risk Minimisation Measures	Routine risk minimisation measures Routine risk communication: SmPC section 4.8 Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC sections 4.2, 4.3 and 4.4 Other risk minimisation measures beyond the Product Information: Medicine's legal status: POM Additional risk minimisation measures Not applicable as there are no additional risk minimisation measures for this safety concern

Table: Important Identified Risk: Increased liver transaminases (Increased liver enzymes)/Hepatic failure (Liver failure)

Risk Minimisation Measures	Routine risk minimisation measures Routine risk communication: SmPC section 4.8 Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC sections 4.2 and 4.4 Other risk minimisation measures beyond the Product Information: Medicine's legal status: POM Additional risk minimisation measures Not applicable as there are no additional risk minimisation measures for this safety concern

Table: Important Identified Risk: Gastrointestinal hemorrhage and ulcers; esophagitis

Risk Minimisation Measures	Routine risk minimisation measures Routine risk communication: SmPC section 4.8 Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC sections 4.4 and 4.5 Other risk minimisation measures beyond the Product Information: Medicine's legal status: POM Additional risk minimisation measures Not applicable as there are no additional risk minimisation measures for this safety concern

Table: Important Identified Risk: Hearing loss

Risk Minimisation Measures	Routine risk minimisation measures Routine risk communication: SmPC section 4.8 Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC section 4.4 Other risk minimisation measures beyond the Product Information: Medicine's legal status: POM Additional risk minimisation measures Not applicable as there are no additional risk minimisation measures for this safety concern

Table: Important Identified Risk: Lens opacities, retinal changes and optic neuritis (Eye disorders: retinal changes and inflammation of the optic nerve)

Risk Minimisation Measures	Routine risk minimisation measures Routine risk communication: SmPC section 4.8

	Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC sections 4.4 and 5.3 Other risk minimisation measures beyond the Product Information: Medicine's legal status: POM <u>Additional risk minimisation measures</u> Not applicable as there are no additional risk minimisation measures for this safety concern

Table: Important Potential Risk: Compliance with posology and biological monitoring

Risk Minimisation Measures	<u>Routine risk minimisation measures</u> Routine risk communication: Not available Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC sections 4.2 and 4.4 Other risk minimisation measures beyond the Product Information: Medicine's legal status: POM <u>Additional risk minimisation measures</u> Educational materials for HCPs and patients

Table: Important Potential Risk: Medication error

Risk Minimisation Measures	<u>Routine risk minimisation measures</u> Routine risk communication: Not available Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC section 4.2 Other risk minimisation measures beyond the Product Information: Medicine's legal status: POM <u>Additional risk minimisation measures</u> Educational materials for HCPs and patients

Table: Missing Information: Long term safety in pediatric NTDT patients aged 10 to 17 years

Risk Minimisation Measures	Routine risk minimisation measures Routine risk communication: Not available Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC sections 4.2 and 4.4 Other risk minimisation measures beyond the Product Information: Medicine's legal status: POM Additional risk minimisation measures Not applicable as there are no additional risk minimisation measures for this safety concern

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 Deferasirox Mylan.

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

There are no studies required for Deferasirox Mylan.