Summary of risk management plan for Deferasirox Accord 90/180/360 mg film-coated tablets (deferasirox)

This is a summary of the risk management plan (RMP) for Deferasirox Accord 90/180/360 mg film-coated tablets. The RMP details important risks of Deferasirox Accord 90/180/360 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Deferasirox Accord 90/180/360 mg film-coated tablet's risks and uncertainties (missing information).

Deferasirox Accord 90/180/360 mg film-coated tablet's product information and its package leaflet give essential information to healthcare professionals and patients on how Deferasirox Accord 90/180/360 mg film-coated tablets should be used.

This summary of the RMP for Deferasirox Accord 90/180/360 mg film-coated tablets 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 European Public Assessment Report for Deferasirox.

Important new concerns or changes to the current ones will be included in updates of Deferasirox Accord 90/180/360 mg film-coated tablet's RMP.

I. The medicine and what it is used for

Deferasirox Accord is indicated 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 Accord is also indicated for the treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups:

- In paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥7 ml/kg/month of packed red blood cells) aged 2 to 5 years,
- In adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<7 ml/kg/month of packed red blood cells) aged 2 years and older,
- In adult and paediatric patients with other anaemias aged 2 years and older.

Deferasirox Accord 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.

Further information about the evaluation of Deferasirox Accord 90/180/360 mg film-coated tablets' benefits can be found in Deferasirox Accord 90/180/360 mg 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-accord.

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

Important risks of Deferasirox Accord 90/180/360 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Deferasirox Accord 90/180/360 mg film-coated tablet'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 Product Information (PI) 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 the case of Deferasirox Accord 90/180/360 mg film-coated tablets, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment and signal management activity, 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 Accord 90/180/360 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Deferasirox Accord 90/180/360 mg 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 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 Deferasirox Accord 90/180/360 mg 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);

Important identified risks	• Renal disorders (increased serum creatinine, acute renal failure (ARF), renal tubular disorders [acquired Fanconi's syndrome]) • Increased liver transaminases / Hepatic failure • Gastrointestinal hemorrhage and ulcers; esophagitis • Hearing loss • Lens opacities, retinal changes and optic neuritis
Important potential risks	• Compliance with posology and biological monitoring • Medication errors [due to switching between formulations (Exjade dispersible tablets/granules and Deferasirox Accord film-coated tablets)]
Missing information	• Long term safety in pediatric NTDT patients aged 10 to 17 years

II.B Summary of important risks with additional risk minimization measures

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Important Potential Risk: **Compliance with posology and biological monitoring**	
Risk minimisation measures	Routine risk minimisation measures: Sections 4.2 and 4.4 of Deferasirox SmPC and corresponding section of PL has information on this safety concern. Other routine risk minimisation measures include the prescription only status of the product. Additional risk minimisation measures: Educational materials for physicians (which also includes a prescriber checklist) and patients
Important Potential Risk: **Medication errors** [due to switching between formulations (Exjade dispersible tablets/granules and Deferasirox Accord film-coated tablets)]	
Risk minimisation measures	Routine risk minimisation measures: Section 4.2 of Deferasirox SmPC and corresponding section of PL has information on this safety concern. Other routine risk minimisation measures include the prescription only status of the product. Additional risk minimisation measures: Educational materials for physicians (which also includes a prescriber checklist) and patients

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 Accord 90/180/360 mg film-coated tablets.

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

There are no studies required for Deferasirox Accord 90/180/360 mg film-coated tablets.