Part VI: Summary of the risk management plan

Summary of risk management plan for **[Deferasirox] 90, 180, 360 mg film-coated tablets**

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

[Deferasirox]'s Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Deferasirox] 90, 180, 360 mg film-coated tablets should be used.

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

I. The medicine and what it is used for

[Deferasirox] 90, 180, 360 mg 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] 90, 180, 360 mg film-coated tablets 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] 90, 180, 360 mg 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 orally.

If important information that may affect the safe use of [Deferasirox] 90, 180, 360 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

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

Important risks of [Deferasirox] 90, 180, 360 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about [Deferasirox] 90, 180, 360 mg 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 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] 90, 180, 360mg 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, 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] 90, 180, 360mg 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] 90, 180, 360mg film-coated tablets that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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] 90, 180, 360mg 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).

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]) • 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
Missing Information	• Long term safety in pediatric NTDT patients aged 10 to 17 years

II.B Summary of important risks

Important Potential Risk: Compliance of the posology and biological monitoring	
Risk minimisation measures	Routine risk minimization measure: – Sections 4.2, 4.4 of SmPC *Other routine risk minimisation measures:* Prescription only medicine Additional risk minimization measures: Educational materials for physicians (Guide for HCPs & Prescriber's Checklist) and information pack for patients regardless of indication.
Important Potential Risk: Medication errors	
Risk minimisation measures	Routine risk minimization measure: – Section 4.2 of SmPC Additional risk minimization measures: Educational materials for physicians and information pack for patients for all the formulations and for all indications and appropriate dosing, to be distributed and prior to launch and after substantial safety modifications of the product information. Introductory notification letter to pharmacists explaining the switch between formulations. Introductory notification letter to prescribers which includes a prescriber's guide and a patient's guide.

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] 90, 180, 360 mg film-coated tablets.

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

There are no studies required for [Deferasirox] 90, 180, 360 mg film-coated tablets.