Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Deferasirox Glenmark (Deferasirox)

This is a summary of the risk management plan (RMP) for deferasirox Glenmark. The RMP details important risks of deferasirox Glenmark, how these risks can be minimised, and how more information will be obtained about deferasirox Glenmark risks and uncertainties (missing information).

Deferasirox Glenmark summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how deferasirox Glenmark should be used.

I. The medicine and what it is used for

Deferasirox Glenmark 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.
- 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.
- 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.

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

Important risks of deferasirox Glenmark, together with measures to minimise such risks and the proposed studies for learning more about deferasirox Glenmark 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 PL 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 PSUR assessment if PSUR is required by Health Authority, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

In the case of deferasirox Glenmark, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

If important information that may affect the safe use of deferasirox Glenmark is not yet available, it is listed under 'missing information' below.

II.A. List of important risks and missing information

Important risks of deferasirox Glenmark are risks 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 Glenmark. 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 risk(s)	• Renal disorders (increased serum creatinine, acute renal failure, renal tubular disorders [acquired Fanconi's syndrome]) • Increased liver transaminases/Hepatic failure • Gastrointestinal haemorrhage and ulcers; esophagitis • Hearing loss • Lens opacities, retinal changes and optic neuritis • Severe cutaneous adverse reactions (including Stevens Johnson syndrome, Toxic epidermal necrolysis and Drug reaction with eosinophilia and systemic symptoms)
Important potential risk(s)	• Compliance with posology and biological monitoring • Medication errors
Missing information	• Long term safety in paediatric non-transfusion-dependent thalassemia patients aged 10 to 17 years

II.B. Summary of important risks

Important Identified Risk – • Renal disorders (increased serum creatinine, acute renal failure [ARF], renal tubular disorders [acquired Fanconi's syndrome])	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s):

Important Identified Risk – • Renal disorders (increased serum creatinine, acute renal failure [ARF], renal tubular disorders [acquired Fanconi's syndrome])	
	SmPC: • Section 4.3: Contraindications • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL:** • Section 2: What you need to know before you take Deferasirox Glenmark • Section 4: Possible side effects Additional risk minimisation measures: None

Important Identified Risk – Increased liver transaminases/Hepatic failure	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects • Section 4.9: Overdose **PL:** • Section 2: What you need to know before you take Deferasirox Glenmark • Section 3: How to take Deferasirox Glenmark • Section 4: Possible side effects Additional risk minimisation measures: None

Important Identified Risk – Gastrointestinal haemorrhage and ulcers; oesophagitis	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.4: Special warnings and precautions for use

Important Identified Risk – Gastrointestinal haemorrhage and ulcers; oesophagitis	
	• Section 4.5: Interaction with other medicinal products and other forms of interaction • Section 4.8: Undesirable effects **PL:** No information is provided in the PL. Additional risk minimisation measures: None

Important Identified Risk – Hearing loss	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL:** • Section 2: What you need to know before you take Deferasirox Glenmark • Section 4: Possible side effects Additional risk minimisation measures: None

Important Identified Risk – Lens opacities, retinal changes and optic neuritis	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL:** • Section 2: What you need to know before you take Deferasirox Glenmark • Section 4: Possible side effects Additional risk minimisation measures:

Important Identified Risk – Lens opacities, retinal changes and optic neuritis	
	None

Important Identified Risk – • Severe cutaneous adverse reactions (SCARs) (including Stevens Johnson syndrome [SJS], Toxic epidermal necrolysis [TEN] and Drug reaction with eosinophilia and systemic symptoms [DRESS])	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL:** • Section 2: What you need to know before you take Deferasirox Glenmark • Section 4: Possible side effects Additional risk minimisation measures: None

Important Potential Risk – Compliance with posology and biological monitoring	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.2: Posology and method of administration • Section 4.4: Special warnings and precautions for use **PL:** • Section 2: What you need to know before you take Deferasirox Glenmark Additional risk minimisation measures: Educational material for HCPs and patients which includes: • Guide for HCPs • Patient Guide

Important Potential Risk – Medication errors	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.2: Posology and method of administration **PL:** Section 3: How to take Deferasirox Glenmark Additional risk minimisation measures: Educational material for HCPs and patients which includes: • Guide for HCPs • Patient Guide

Missing information – Long term safety in paediatric non-transfusion-dependent thalassaemia (NTDT) patients aged 10 to 17 years	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.2: Posology and method of administration • Section 4.4: Special warnings and precautions for use **PL:** • Section 1: What Deferasirox Glenmark is and what it is used for Additional risk minimisation measures: None

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 Glenmark.

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

There are no studies required for deferasirox Glenmark.