Part VI: Summary of the risk management plan

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

Deferasirox Jubilant summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Deferasirox Jubilant 90 mg, 180 mg and 360 mg film-coated tablets should be used.

I. The medicine and what it is used for

Deferasirox Jubilant 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. It contains Deferasirox as the active substance and it is given by oral route.

Deferasirox Jubilant 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 Jubilant is also indicated for the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusiondependent 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 Jubilant, together with measures to minimise such risks for learning more about Deferasirox Jubilant 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 case of Deferasirox Jubilant, these measures are supplemented with additional risk minimization measures mentioned under relevant important risks section II.B.

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 Jubilant is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Deferasirox Jubilant 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 Jubilant. 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 haemorrhage and ulcers; esophagitis • Hearing loss • Lens opacities, retinal changes and optic neuritis • Severe cutaneous adverse reactions (SCARs) (including Stevens-Johnson syndrome [SJS], Toxic epidermal

List of important risks and missing information	
	necrolysis [TEN] and Drug Reaction with eosinophilia and systemic symptoms [DRESS])
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 • Safety of new formulation (FCT/granules)

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product. The summary of important risks is as below:

Important Identified Risks:

Renal disorders (increased serum creatinine, acute renal failure, renal tubular disorders acquired Fanconi's syndrome])	
Evidence for linking the risk to the medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk factors and risk groups	Patients treated with deferasirox
Risk minimisation measures	**Routine risk minimization measures:** SmPC Section 4.2 Posology and method of administration, 4.3 Contraindications, and 4.4 Special warnings and precautions for use. Relevant terms are included as Adverse Drug Reactions (ADRs) in SmPC Section 4.8 Undesirable effects. **Additional risk minimization measures:** None

Increased liver transaminases / Hepatic failure	
Evidence for linking the risk to the medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk factors and risk groups	Patients treated with deferasirox
Risk minimisation measures	**Routine risk minimization measures:** SmPC Section 4.2 Posology and method of administration, 4.4 Special warnings and precautions

	for use. Relevant terms are included as ADRs in SmPC Section 4.8 Undesirable effects. **Additional risk minimization measures:** None

Gastrointestinal haemorrhage and ulcers; esophagitis	
Evidence for linking the risk to the medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk factors and risk groups	Patients treated with deferasirox
Risk minimisation measures	**Routine risk minimization measures:** SmPC Section 4.4 Special warnings and precautions for use, and 4.5 Interaction with other medicinal products and other forms of interaction. Relevant terms are included as ADRs in SmPC Section 4.8 Undesirable effects. **Additional risk minimization measures:** None

Hearing loss	
Evidence for linking the risk to the medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk factors and risk groups	Patients treated with deferasirox
Risk minimisation measures	**Routine risk minimization measures:** SmPC Section 4.4 Special warnings and precautions for use. Relevant terms are included as ADRs in SmPC Section 4.8 Undesirable effects. **Additional risk minimization measures:** None

Lens opacities, retinal changes and optic neuritis	
Evidence for linking the risk to the medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk factors and risk groups	Patients treated with deferasirox

Risk minimisation measures	**Routine risk minimization measures:** SmPC Section 4.4 Special warnings and precautions for use, 5.3 Preclinical safety data. Relevant terms are included as ADRs in SmPC Section 4.8 Undesirable effects. **Additional risk minimization measures:** None

Severe cutaneous adverse reactions (SCARs) (including Stevens-Johnson syndrome [SJS], Toxic epidermal necrolysis [TEN] and Drug Reaction with eosinophilia and systemic symptoms [DRESS])	
Evidence for linking the risk to the medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk factors and risk groups	Patients treated with deferasirox
Risk minimisation measures	**Routine risk minimization measures:** SmPC Section 4.4 Special warnings and precautions for use. Relevant terms are included as ADRs in SmPC Section 4.8 Undesirable effects. **Additional risk minimization measures:** None

Long term safety in paediatric NTDT patients aged 10 to 17 years	
Risk minimisation measures	**Routine risk minimization measures:** SmPC Section 4.2 Posology and method of administration, 4.4 Special warnings and precautions for use **Additional risk minimization measures:** None
Additional pharmacovigilance activities	None

Important Potential Risks

Compliance with posology and biological monitoring	
Evidence for linking the risk to the medicine	In line with the reference RMP, this safety concern has been classified as an important potential risk.
Risk factors and risk groups	Patients treated with deferasirox

Risk minimisation measures	**Routine risk minimization measures:** SmPC Section 4.2 Posology and method of administration and 4.4 Special warnings and precautions for use **Additional risk minimization measures:** Educational materials for physicians and patients regardless of the indication

Medication errors	
Evidence for linking the risk to the medicine	In line with the reference RMP, this safety concern has been classified as an important potential risk.
Risk factors and risk groups	Patients treated with deferasirox
Risk minimisation measures	**Routine risk minimization measures:** SmPC Section 4.2 Posology and method of administration **Additional risk minimization measures:** Educational materials for physicians and patients for all the formulations and for all indications describing the new deferasirox formulation (FCT/granules) and appropriate dosing. Introductory notification letters will be distributed to the prescribers and pharmacists, describing the new FCT, providing information on dosing and administration and explaining the switch between formulations.

Missing information

Long term safety in paediatric NTDT patients aged 10 to 17 years	
Risk minimisation measures	**Routine risk minimization measures:** SmPC Section 4.2 Posology and method of administration, 4.4 Special warnings and precautions for use **Additional risk minimization measures:** None

Safety of new formulation (FCT/granules)	
Risk minimisation measures	**Routine risk minimization measures:**

	SmPC Section 4.2 Posology and method of administration, 5.2 Pharmacokinetic properties and Patient Leaflet **Additional risk minimization 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 Jubilant.

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

There are no studies required for Deferasirox Jubilant.