13 Part VI: Summary of the risk management plan (RMP) – Deferasirox*, 90 mg, 180 mg and 360 mg, Film-coated tablets

invented names in RMS - AT

Deferasirox Sandoz 90 mg - Filmtabletten

Deferasirox Sandoz 180 mg - Filmtabletten

Deferasirox Sandoz 360 mg – Filmtabletten

and

Ferupantil 90 mg - Filmtabletten

Ferupantil 180 mg - Filmtabletten

Ferupantil 360 mg - Filmtabletten

This is a summary of the RMP for deferasirox, 90 mg, 180 mg and 360 mg, film-coated tablets. The RMP details important risks of deferasirox film-coated tablets, how these risks can be minimized, and how more information will be obtained about deferasirox film-coated tablets' risks and uncertainties (missing information).

Deferasirox, film-coated tablets' summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how deferasirox film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of the deferasirox, film-coated tablets' RMP.

13.1 Part VI: I. The medicine and what it is used for

Deferasirox 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 thalassemia major aged 6 years and older.

Deferasirox 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 pediatric patients with beta thalassemia 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 pediatric patients with beta thalassemia 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 pediatric patients with other anemias aged 2 years and older.

Deferasirox 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 thalassemia (NTDT) syndromes aged 10 years and older.

It contains deferasirox as an active substance and is taken orally as film-coated tablets (90 mg, 180 mg and 360 mg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of deferasirox film-coated tablets, together with measures to minimize such risks are outlined below.

Measures to minimize 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 HCPs;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In the case of deferasirox, film-coated tablets, these measures are supplemented with *additional risk minimization measures* mentioned under relevant important risks, below.

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

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of deferasirox, film-coated tablets are risks that need special risk management activities to further investigate or minimize 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, 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
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

	Severe cutaneous adverse reactions (SCARs) (including Stevens-Johnson syndrome [SJS], Toxic epidermal 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 pediatric NTDT patients aged 10 to 17 years
	Safety of new formulation (film-coated tablets)

13.2.2 Part VI – II.B: Summary of important risks

Table 13-2 Important potential risk: Compliance with posology and biological monitoring

Risk minimization measures	**Routine risk minimization measures:** SmPC sections 4.2 and 4.4 **Legal status:** Prescription only **Additional risk minimization measures:** Education materials: Guide for HCPs, Prescriber checklist and Patient guide

Table 13-3 Important potential risk: Medication errors

Risk minimization measures	**Routine risk minimization measures:** SmPC section 4.2 **Legal status:** Prescription only **Additional risk minimization measures:** Education materials: Guide for HCPs, Prescriber checklist and Patient guide

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of deferasirox, film-coated tablets.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for deferasirox, film-coated tablets.