Part VI: Summary of the risk management plan

Summary of risk management plan for Deferasirox Sigillata (deferasirox)

This is a summary of the risk management plan (RMP) for Deferasirox Sigillata 125mg, 250mg and 500mg dispersible tablets. The RMP details important risks of Deferasirox Sigillata, how these risks can be minimised, and how more information will be obtained about Deferasirox Sigillata's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Deferasirox Sigillata is authorised for chronic iron overload (see SmPC for the full indication). It contains deferasirox as the active substance and it is given orally as dispersible tablets.

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

Important risks of Deferasirox Sigillata, together with measures to minimise such risks and the proposed studies for learning more about Deferasirox Sigillata'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 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 Sigillata, 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 Sigillata is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Deferasirox Sigillata 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 Sigillata. 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);

Summary of safety concerns	
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
Important potential risks	• Compliance with posology and biological monitoring • Medication errors due to switching between Exjade FCT/granules and generic versions of deferasirox DT
Missing information	• Long term safety in paediatric NTDT patients aged 10 to 17 years • Safety of new formulation (FCT)

II.B Summary of important risks

Important potential risk 1: Compliance with posology and biological monitoring	
Risk minimisation measures	**Routine risk minimisation measures:** Information is included in Sections 4.2 and 4.4 of the SmPC that state the starting and adjustment doses and the requirement for regular tests. Section 3 of the PIL. Treatment with deferasirox should be initiated and maintained by physicians experienced in the treatment of chronic iron overload. **Additional risk minimisation measures:** Educational materials for physicians (which also includes a physicians' checklist) and patients regardless of indication.

Important potential risk 2: Medication error due to switching between Exjade FCT/granules and generic versions of deferasirox DT	
Risk minimisation measures	**Routine risk minimisation measures:** Information is included in Sections 4.2 and 4.4 of the SmPC that state the starting and adjustment doses and the requirement for regular tests. Section 3 of the PIL. Treatment with deferasirox should be initiated and maintained by physicians experienced in the treatment of chronic iron overload. **Additional risk minimisation measures:** Educational materials for physicians (which also includes a physicians' checklist) and patients clarifying the dose adjustment requirements in case of switch between Exjade FCT/granules and generic versions of deferasirox DT.