Summary of risk management plan for Deferiprone DOC and DEFERIPRONE DOC

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

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

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

I. The medicine and what it is used for

Deferiprone is authorised for monotherapy for the treatment of iron overload in patients with thalassaemia major when current chelation therapy is contraindicated or inadequate.

Deferiprone DOC and DEFERIPRONE DOC in combination with another chelator is indicated in patients with thalassaemia major when monotherapy with any iron chelator is ineffective, or when prevention or treatment of life-threatening consequences of iron overload (mainly cardiac overload) justifies rapid or intensive correction.

It contains deferiprone, as the active substance and it is given by oral route of administration of 500 mg and 1000 mg film-coated tablets.

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

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

II.A List of important risks and missing information

Important risks of deferiprone 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 deferiporne. 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	• Agranulocytosis • Neutropenia • Use in pregnancy
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Agranulocytosis Important identified risk	
Risk minimisation measures	Routine risk minimisation measures: *SmPC sections 4.3, 4.4 and 4.8.* – Prescription only medicine. Additional risk minimisation measures: Patient card (part of the labelling and Package leaflet)

Neutropenia

Important identified risk	
Risk minimisation measures	Routine risk minimisation measures: *SmPC sections 4.3, 4.4 and 4.8.* – Prescription only medicine. Additional risk minimisation measures: Patient card (part of the labelling and Package leaflet)

Use in pregnancy Important identified risk	
Risk minimisation measures	Routine risk minimisation measures: *SmPC sections 4.3, 4.6 and 5.3.* – Prescription only medicine. 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 deferiprone products covered by this RMP.

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

There are no studies required for deferiprone products covered by this RMP.