Part VI: Summary of the risk management plan

Summary of risk management plan for Deferiprone Lipomed 500 mg film-coated tablets

(Deferiprone)

This is a summary of the risk management plan (RMP) for Deferiprone Lipomed 500 mg film-coated tablets. The RMP details important risks of the product and how these risks can be minimised.

The summary of product characteristics (SmPC) for Deferiprone Lipomed 500 mg film-coated tablets and its package leaflet (PL) give essential information to healthcare professionals and patients on how the product should be used.

This summary of the RMP for Deferiprone Lipomed 500 mg film-coated tablets should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Deferiprone Lipomed 500 mg film-coated tablets is used to treat iron overload in patients with thalassaemia major when current chelation therapy is contraindicated or inadequate (see SmPC for the full indication). It contains deferiprone as the active substance and it is given as 500 mg film-coated tablets.

Further information about the evaluation of the benefits of Deferiprone Lipomed 500 mg film-coated tablets can be found in the product's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage (https://www.ema.europa.eu/en/medicines/human/EPAR/deferiprone-lipomed).

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

Important risks of Deferiprone Lipomed 500 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about the product'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 Lipomed 500 mg film-coated tablets, 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*.

II.A List of important risks and missing information

Important risks of Deferiprone Lipomed 500 mg film-coated tablets 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 Deferiprone Lipomed 500 mg 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).

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	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> • Routine risk communication in SmPC sections 4.3, 4.4 and 4.8 / PL sections 2 and 4 • Recommendation for specific clinical measures in SmPC section 4.4 regarding monitoring of patient's neutrophil count and management of patients who experience agranulocytosis • Prescription only <u>Additional risk minimisation measures:</u> • Wallet-sized patient card provided in the folding box

Neutropenia	
Risk minimisation measures	Routine risk minimisation measures: • Routine risk communication in SmPC sections 4.3, 4.4 and 4.8 / PL sections 2 and 4 • Recommendation for specific clinical measures in SmPC section 4.4 regarding monitoring of patient's neutrophil count and management of patients who experience neutropenia • Prescription only Additional risk minimisation measures: • Wallet-sized patient card provided in the folding box

Use in pregnancy	
Risk minimisation measures	Routine risk minimisation measures: • Routine risk communication in SmPC section 4.3, 4.6, 5.3 / PL section 2; • Prescription only Additional risk minimisation measures: • Wallet-sized patient card provided in the folding box

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 Lipomed 500 mg film-coated tablets.

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

There are no studies required for Deferiprone Lipomed 500 mg film-coated tablets.