Part VI: Summary of the risk management plan for Deferipron Orifarm

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

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

I. The medicine and what it is used for

Deferipron Orifarm is authorised for the treatment of 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 substances and it is given orally as film-coated tablets.

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

Important risks of Deferipron Orifarm, together with measures to minimise such risks and the proposed studies for learning more about Deferipron Orifarm's risks, are outlines below.

- Product information including warnings, precautions, and advice on correct use. Package leaflet is enclosed in the package and the Summary of Product Characteristics (and Package Leaflet) are published on the webpage of the Danish Medicines Agency.
- The medicine's is prescription only medicine and must be prescribed by a doctor.

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

In the case of Deferipron Orifarm 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 Deferipron Orifarm is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Deferipron Orifarm 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 Deferipron Orifarm. 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	• Agranulocytosis • Neutropenia • Use in pregnancy
Important potential risks	None
Missing information	None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Agranulocytosis	
Risk minimisation measures	Routine risk minimisation measures: SmPC for healthcare professionals and PIL for patients include information regarding the risk. Routine risk communication in SmPC sections 4.3, 4.4, 4.5 and 4.8 / PL section 2 and 4. Recommendation for specific clinical measures in SmPC section 4.4. Additional risk minimisation measures: Patient/carer reminder card in each package.

Neutropenia	
Risk minimisation measures	Routine risk minimisation measures: SmPC for healthcare professionals and PIL for patients include information regarding the risk. Routine risk communication in SmPC sections 4.3, 4.4, 4.5 and 4.8 / PL section 2 and 4. Recommendation for specific clinical measures in SmPC section 4.4. Additional risk minimisation measures: Patient/carer reminder card in each package.

Use in pregnancy	
Risk minimisation measures	Routine risk minimisation measures: SmPC for healthcare professionals and PIL for patients include information regarding the risk. Routine risk communication in SmPC section 4.3, 4.6, 5.3 /

Use in pregnancy	
	PL section 2. <u>Additional risk minimisation measures</u>: Patient/carer reminder card in each package.

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 Deferipron Orifarm.

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

There are no studies required for Deferipron Orifarm.