Part VI: Summary of the risk management plan

Summary of risk management plan for Monofer® and Diafer®

This is a summary of the Risk Management Plan (RMP) for Monofer® and Diafer®. The RMP details important risks of Monofer® and Diafer®, how these risks can be minimised, and how more information will be obtained about Monofer® and Diafer®'s risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Monofer® is authorised in adults for the treatment of iron deficiency in the following conditions:

- When oral iron preparations are ineffective or cannot be used
- Where there is a clinical need to deliver iron rapidly

Diafer® is authorised in adults for the treatment of iron deficiency in patients with chronic kidney disease (CKD) on dialysis.

See SmPCs for the full indication.

Both products contains Iron (III) isomaltoside 1000/Ferric derisomaltose as the active substance and it is given intravenously.

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

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

II.A List of important risks and missing information

Important risks of Monofer® and Diafer® 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 Monofer® and Diafer®. 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	Hypersensitivity reactions
Important potential risks	None
Missing information	Pregnant and lactating women

II.B Summary of important risk

Important identified risk: Hypersensitivity	
Evidence for linking the risk to the medicine	Strong evidence of class effect based on literature review, review of the Pharmacosmos A/S safety database, and the Referral procedure (EMEA/H/A-31/1322).

Risk factors and risk groups	The risk is enhanced for patients with known allergies including drug allergies, including patients with a history of severe asthma, eczema, or other atopic allergy. There is also an increased risk of hypersensitivity reactions to parenteral iron complexes in patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis).
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.2 Administration SmPC section 4.3 Contraindications SmPC section 4.4 Special warning and precautions for use SmPC section 4.8 Undesirable effects Additional risk minimisation measures: Direct Healthcare Professional Communication (DHPC) Educational material (Checklist) to healthcare professionals
Additional pharmacovigilance activities	NA

Important identified risk: Use in pregnancy and breast feeding	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.6 Fertility, pregnancy and lactation Additional risk minimisation measures: Direct Healthcare Professional Communication (DHPC) Educational material (Checklist) to healthcare professionals
Additional pharmacovigilance activities	NA

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

Not applicableII.C.2 Other studies in post-authorisation development plan

There are no studies required for Monofer® and Diafer®.