Part VI: Summary of the risk management plan

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

Cosmofer's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Cosmofer® should be used.

I. The medicine and what it is used for

Cosmofer® is authorised 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

See SmPCs for the full indication.

The product contains Iron dextran as the active substance and it is given intravenously or intramuscularly.

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

Important risks of Cosmofer® together with measures to minimise such 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 Cosmofer®, 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 CosmoFer® is not yet available, it is listed under 'missing information' below.

II.A List of important risk and missing information

Important risks of CosmoFer® 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 CosmoFer®. 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 Use in children < 14 years of age

II.B Summary of important risks

Important identified risk: Hypersensitivity	
Evidence for linking the risk to the medicine	Strong evidence of class effect based 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 SmPC section 4.3

	SmPC section 4.4 SmPC section 4.8 PIL section 2 where advice is given on allergic reactions PIL section 4 Additional risk minimisation activities: Educational material for patients and the healthcare professionals prescribing the IV iron medicinal products to the patients
Additional pharmacovigilance activities	None

Missing information: Use in pregnancy and breast feeding	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.6 SmPC section 4.8 PIL section 2 where advice is given on pregnancy and breast-feeding
Additional pharmacovigilance activities	None

Missing information: Use in children < 14 years of age	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.1 SmPC section 4.2 PIL section 2 where advice is given on children
Additional pharmacovigilance activities	None

II.C Post-authorisation development plan

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

Not applicable.

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

There are no studies required for CosmoFer®.