Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for Ferric carboxymaltose 50 mg iron/ml dispersion for injection/infusion* (Ferric carboxymaltose)

*In RMS-AT:

- **Eisen-Carboxymaltose ratiopharm 50 mg Eisen/ml Dispersion zur Injektion/Infusion (for procedure AT/H/1319/001/DC)**
- **Eisen-Carboxymaltose TEVA 50 mg Eisen/ml Dispersion zur Injektion/Infusion (for procedure AT/H/1318/001/DC)**

This is a summary of the risk management plan (RMP) for Ferric carboxymaltose 50 mg iron/ml dispersion for injection/infusion (hereinafter referred to as Ferric carboxymaltose). The RMP details important risks of Ferric carboxymaltose, how these risks can be minimised, and how more information will be obtained about Ferric carboxymaltose's risks and uncertainties (missing information).

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

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

I. The Medicine and What It is used for

Ferric carboxymaltose 50 mg iron/ml dispersion for injection/infusion is authorised for the treatment of iron deficiency when:

- oral iron preparations are ineffective.
- oral iron preparations cannot be used.
- there is a clinical need to deliver iron rapidly (see SmPC for the full indication).

It contains Ferric carboxymaltose as the active substance and it is administered intravenously.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

II.A List of Important Risks and Missing Information

Important risks of Ferric carboxymaltose 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 Ferric carboxymaltose. 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).

Table 19: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	• Hypersensitivity/anaphylactic reaction • Hypophosphataemic osteomalacia
Important potential risks	• None
Missing information	• Use in pregnant or lactating women • Use in patients with hepatic impairment • Use in patients with infectious diseases • Long-term usage

II.B Summary of Important Risks

Table 20: Summary of Additional Risk Minimisation Measures by Safety Concern

Important identified risk: Hypersensitivity/anaphylactic reaction	
Evidence for linking the risk to the medicine	SmPC
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 (SmPC section 4.4). 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) (SmPC section 4.4).
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.2, 4.3, 4.4 and 4.8. PL sections 2, 3 and 4. Prescription only medicine. Additional risk minimisation measures Educational Materials for Physicians and Patients (Prescriber Guide, Patient Guide)
Additional pharmacovigilance activities	Cumulative annual review of hypersensitivity reactions (commitment from the Article 31 EMA referral procedure; EMEA/H/A-31/1322), to be included within the PSUR for ferric carboxymaltose in the EEA.
Missing information: Use in pregnant or lactating women	
Evidence for linking the risk to the medicine	SmPC
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.6, 5.1 and 5.3. PL section 2. Prescription only medicine. Additional risk minimisation measures Educational Materials for Physicians and Patients (Prescriber Guide, Patient Guide)
Additional pharmacovigilance activities	Cumulative annual review of pregnancies (commitment from the Article 31 EMA referral procedure; EMEA/H/A-31/1322), to be included within the PSUR for ferric carboxymaltose in the EEA.

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 for Teva's Ferric carboxymaltose.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Teva's Ferric carboxymaltose.