## Part VI: Summary of the risk management plan

### Summary of risk management plan for "Ferric carboxymaltose, 50 mg/ml, solution for injection/infusion"

This is a summary of the risk management plan (RMP) for ferric carboxymaltose, 50 mg/ml, solution for injection/infusion. The RMP details important risks of ferric carboxymaltose, solution for injection/infusion, how these risks can be minimized, and how more information will be obtained about ferric carboxymaltose, solution for injection/infusion's risks and uncertainties (missing information).

Ferric carboxymaltose, solution for injection/infusion's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how ferric carboxymaltose, solution for injection/infusion should be used.

Important new concerns or changes to the current ones will be included in updates of the ferric carboxymaltose, solution for injection/infusion's RMP.

### I. The medicine and what it is used for

Ferric carboxymaltose, solution for injection/infusion is authorized for:

Ferric carboxymaltose is indicated 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.

The diagnosis of iron deficiency must be based on laboratory tests.

It contains ferric carboxymaltose as active substance and is given through intravenous route (IV) as solution for injection/infusion (50 mg/ml).

### II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of ferric carboxymaltose solution for injection/infusion, together with measures to minimize such risks and the proposed studies for learning more about ferric carboxymaltose solution for injection/infusion risks, are outlined below.

Measures to minimize 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 authorized 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 minimize its risks.

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

In the case of ferric carboxymaltose solution for injection/infusion, these measures are supplemented with additional risk minimization measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 solution for injection/infusion 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 solution for injection/infusion are risks that need special risk management activities to further investigate or minimize 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 solution for injection/infusion. 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/ anaphylactoid reaction |
| Important potential risks | None |
| Missing information | Use in pediatric population |
| | Use in elderly patients |
| | Use in patients with infectious diseases |
| | Use in pregnant or lactating women |

### *II.B Summary of important risks*

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

| **Important identified risk: Hypersensitivity/ anaphylactoid reaction** | |
|---|---|
| Risk minimization measures | **Routine risk minimization measures:**<br>SmPC Sections 4.2, 4.3, 4.4, 4.6 and 4.8.<br>PL Sections 2, 3, 4 and Section "The following information is intended for healthcare professionals only".<br>**Routine risk minimization activities recommending specific clinical measures to address the risk:**<br>SmPC Sections 4.2 and 4.4 and PL Sections 3: |

| | |
|---|---|
| **Important identified risk: Hypersensitivity/ anaphylactoid reaction** | |
| | Recommended to monitor the patient carefully for signs and symptoms of hypersensitivity reactions during and following each administration. Ferric carboxymaltose, 50 mg/ ml, solution for injection/ infusion should only be administered when staff trained to evaluate and manage anaphylactic reactions are immediately available, in an environment where full resuscitation facilities can be assured. Each patient should be observed for adverse effects for at least 30 minutes following each administration.<br>**Other routine risk minimization measures beyond the Product Information:**<br>• **Legal status:** Prescription-only medicine.<br>• **Pack Sizes:**<br>- 2 mL solution containing 100 mg iron. Available in pack sizes of 1, 2 and 5 vials.<br>- 10 mL solution containing 500 mg iron. Available in pack sizes of 1, 2 and 5 vials<br>- 20 mL solution containing 1,000 mg iron. Available in a pack size of 1 vial<br>**Additional risk minimization measures:**<br>**Educational Materials:**<br>• HCP Guide<br>• Patient Guide |
| **Missing information: Use in pregnant or lactating women** | |
| Risk minimization measures | **Routine risk minimization measures:**<br>SmPC Sections 4.6 and 5.1.<br>PL Section 2 and Section "The following information is intended for healthcare professionals only".<br>**Routine risk minimization activities recommending specific clinical measures to address the risk:**<br>SmPC Sections 4.6 and 5.1: A careful benefit/risk evaluation is required before use during pregnancy and ferric carboxymaltose, 50 mg/ ml, solution for injection/ infusion should not be used during pregnancy unless deemed necessary.<br>Treatment should be confined to the second and third trimester if the benefit is judged to outweigh the potential risk for both the mother and the fetus.<br>The unborn baby should be carefully monitored during intravenous administration of parenteral irons to pregnant women.<br>**Other routine risk minimization measures beyond the Product Information:**<br>• **Legal status:** Prescription-only medicine.<br>• **Pack Sizes:**<br>- 2 mL solution containing 100 mg iron. Available in pack sizes of 1, 2 and 5 vials.<br>- 10 mL solution containing 500 mg iron. Available in pack sizes of 1, 2 and 5 vials |

| Important identified risk: Hypersensitivity/ anaphylactoid reaction | |
|---|---|
| | - 20 mL solution containing 1,000 mg iron. Available in a pack size of 1 vial<br>**Additional risk minimization measures:**<br>**<u>Educational Materials:</u>**<br>• HCP Guide<br>• Patient Guide |

## *II.C Post-authorization development plan*

### II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of ferric carboxymaltose, 50 mg/ml, solution for injection/infusion.

### II.C.2 Other studies in post-authorization development plan

There are no studies required for ferric carboxymaltose, 50 mg/ml, solution for injection/infusion.