SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CORIFER INJECTION. (Iron Sucrose Injection USP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Ferric Hydroxide in complex with Sucrose

Eq to Elemental Iron ……..20 mg.

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intravenous Injection. A reddish brown coloured solution filled in a 5ml amber coloured glass ampoule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CORIFER INJECTION is an iron replacement product indicated for the treatment of iron deficiency anaemia in patients with chronic kidney disease (CKD).

4.2 Posology and method of administration

Adult patients

Hemodialysis Dependent-CKD (HDD-CKD): 100 mg slow intravenous injection or infusion. Non-Dialysis Dependent-CKD (NDD-CKD): 200 mg slow intravenous injection. Peritoneal Dialysis Dependent-CKD (PDD-CKD): 300 mg or 400 mg intravenous infusion.

Paediatric patients

HDD-CKD, NDD-CKD or PDD-CKD: 0.5 mg/kg slow intravenous injection or infusion.

Route of Administration

Intravenous.

4.3 Contraindications

Known hypersensitivity to CORIFER INJECTION.

4.4 Special warnings and precautions for use

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylactic-type reactions, some life-threatening and fatal, have been reported. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Discontinue immediately if hypersensitivity or intolerance signs occur; monitor for at least 30 minutes and until clinically stable after infusion completion. Only administer when personnel and therapies for treating serious hypersensitivity reactions are immediately available.

Hypotension

May cause clinically significant hypotension, potentially related to rate of administration and/or total dose. Monitor for signs and symptoms following each administration.

Iron Overload

Excessive parenteral iron therapy can lead to iatrogenic haemosiderosis. Periodic monitoring of haematologic and iron parameters (haemoglobin, haematocrit, serum ferritin, transferrin saturation) is required. Do not administer to patients with evidence of iron overload. Transferrin saturation values increase rapidly after IV iron sucrose administration; do not perform serum iron measurements for at least 48 hours after dosing.

4.5 Pregnancy and lactation

Pregnancy

No adequate and well-controlled studies in pregnant women. Animal reproduction studies in rats and rabbits at doses up to 13 mg/kg/day of elemental iron showed no evidence of harm to the fetus. CORIFER INJECTION should be used during pregnancy only if clearly needed.

Lactation

Not known whether iron sucrose is excreted in human milk; secreted into milk of lactating rats. Caution should be exercised when administered to a nursing woman.

4.6 Effects on ability to drive and use machines

There are no data about the effect of this product on driving capacity. An effect is, however, unlikely.

4.7 Undesirable effects

Frequencies defined as: uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); common (≥1/100 to <1/10).

Immune system disorders

Uncommon: Hypersensitivity reactions. Rare: Anaphylactoid reactions.

Nervous system disorders

Common: Headache, dizziness. Uncommon: Paraesthesia, dysgeusia. Rare: Loss of consciousness.

Cardiac disorders

Uncommon: Tachycardia.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

4.9 Overdosage

No data are available regarding overdosage of CORIFER INJECTION in humans. Excessive dosages may lead to accumulation of iron in storage sites, potentially leading to haemosiderosis. Do not administer to patients with iron overload. In single-dose studies in mice and rats at IV iron sucrose doses up to 8 times the maximum recommended human dose (based on body surface area), toxicities included sedation, hypoactivity, pale eyes, bleeding in the gastrointestinal tract and lungs, and mortality.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

CORIFER INJECTION is an aqueous complex of poly-nuclear iron (III)-hydroxide in sucrose. Following IV administration, it dissociates into iron and sucrose; iron is transported as a complex with transferrin to target cells including erythroid precursor cells, where it is incorporated into haemoglobin as cells mature into red blood cells. In 22 haemodialysis patients receiving erythropoietin therapy treated with iron sucrose (100 mg, three times weekly for three weeks), significant increases in serum iron and serum ferritin and significant decreases in total iron binding capacity occurred four weeks from initiation of treatment.

5.2 Pharmacokinetic Properties

In healthy adults, the iron component exhibited first order kinetics with an elimination half-life of 6 hours, total clearance of 1.2 L/h, and steady state apparent volume of distribution of 7.9 L, distributing mainly in blood and to some extent extravascular fluid. A study using 52Fe/59Fe-labelled iron sucrose (100 mg) in iron-deficient patients showed significant distribution to the liver, spleen and bone marrow, with bone marrow acting as an irreversible iron trapping compartment.

The sucrose component is eliminated mainly by urinary excretion; in a study with 1,510 mg sucrose/100 mg iron in 12 healthy adults, 68.3% of sucrose was eliminated in urine in 4 hours and 75.4% in 24 hours. Approximately 5% of iron was eliminated in urine in 24 hours in patients on erythropoietin therapy. The effects of age and gender on pharmacokinetics have not been studied.

5.3 Preclinical Safety Data

Carcinogenicity studies have not been performed with iron sucrose. It was not mutagenic in the bacterial reverse mutation assay (Ames test) or mouse lymphoma assay, and not clastogenic in the in vitro chromosome aberration assay or in vivo mouse micronucleus assay. At intravenous doses up to 15 mg/kg/day of elemental iron (1.2 times the maximum recommended human dose), no effect on fertility or reproductive function of male and female rats was observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Sodium Hydroxide BP
- Water for Injections BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months.

6.4 Special precautions for storage

Store below 30°C in dry place. Protect from light.

6.5 Nature and Content of Container

5 ml amber coloured glass ampoule. Such 5 ampoules packed in a tray; such tray packed in carton along with pack insert.

6.6 Special precaution for disposal and other handling

None.

7. MARKETING AUTHORISATION HOLDER

Signature Healthcare Limited,

Cape Business Park, Along Thika Super Highway,

P.O. Box 66172-00800,

Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER(S)

H2022/CTD9121/20248

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

9-11-2022

10. DATE OF REVISION OF THE TEXT

22-08-2026