SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Tawfer

2. Qualitative and quantitative composition

Each mL contains:

Ferric Hydroxide in Complex with Sucrose equivalent to Elemental Iron 20 mg

3. Pharmaceutical form

Solution for injection/infusion.

4. Clinical particulars

4.1 Therapeutic indications

Iron Sucrose Injection BP 20 mg/mL is indicated for the treatment of iron deficiency in the following indications:

- where there is a clinical need for a rapid iron supply;
- in patients who cannot tolerate oral iron therapy or who are non-compliant;
- in active inflammatory bowel disease where oral iron preparations are ineffective;
- in chronic kidney disease when oral iron preparations are less effective.
- The diagnosis of iron deficiency must be based on appropriate laboratory tests, e.g. Hb, serum ferritin, TSAT, serum iron, etc.

4.2 Posology and method of administration

Patients should be monitored carefully for signs and symptoms of hypersensitivity reactions during and following each administration of Iron Sucrose Injection BP 20 mg/mL.

Iron Sucrose Injection BP 20 mg/mL 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. The patient should be observed for adverse effects for at least 30 minutes following each administration.

The cumulative dose of Iron Sucrose Injection BP 20 mg/mL must be calculated for each patient individually and must not be exceeded.

The total cumulative dose, equivalent to the total iron deficit (mg), is determined by the haemoglobin level (Hb) and body weight (BW). The dose must be individually calculated according to the total iron deficit calculated with the Ganzoni formula:

Total iron deficit [mg] = BW [kg] x (target Hb - actual Hb) [g/dL] x 2.4 + storage iron [mg]

Below 35 kg body weight: Target Hb = 13 g/dL and storage iron = 15 mg/kg body weight. For 35 kg body weight and above: Target Hb = 15 g/dL and storage iron = 500 mg.

Factor 2.4 = 0.0034 (iron content of Hb = 0.34%) x 0.07 (blood volume = 7% of body weight) x 1000 (conversion of g to mg) x 10.

Total product to be administered (mL) = Total iron deficit (mg) / 20 mg iron per mL.

Total amount of product to be administered according to body weight, actual Hb level and target Hb level:

Body weight	Hb 6.0 g/dL	Hb 7.5 g/dL	Hb 9.0 g/dL	Hb 10.5 g/dL
30 kg	47.5 mL	42.5 mL	37.5 mL	32.5 mL
35 kg	62.5 mL	57.5 mL	50 mL	45 mL
40 kg	67.5 mL	60 mL	55 mL	47.5 mL
45 kg	75 mL	65 mL	57.5 mL	50 mL
50 kg	80 mL	70 mL	60 mL	52.5 mL
55 kg	85 mL	75 mL	65 mL	55 mL
60 kg	90 mL	80 mL	67.5 mL	57.5 mL
65 kg	95 mL	82.5 mL	72.5 mL	60 mL
70 kg	100 mL	87.5 mL	75 mL	62.5 mL
75 kg	105 mL	92.5 mL	80 mL	65 mL
80 kg	112.5 mL	97.5 mL	82.5 mL	67.5 mL
85 kg	117.5 mL	102.5 mL	85 mL	70 mL
90 kg	122.5 mL	107.5 mL	90 mL	72.5 mL

If the total necessary dose exceeds the maximum allowed single dose, the administration must be divided.

Adults: 5-10 mL of Iron Sucrose Injection BP 20 mg/mL (100-200 mg iron), 1 to 3 times a week. For administration time and dilution ratio, see method of administration.

Paediatric population: The use of Iron Sucrose Injection BP 20 mg/mL has not been adequately studied in children and is therefore not recommended for use in children.

Method of administration: Iron Sucrose Injection BP 20 mg/mL must only be administered by the intravenous route. This may be by slow intravenous injection, by intravenous drip infusion or directly into the venous line of the dialysis machine.

Intravenous drip infusion: Iron Sucrose Injection BP 20 mg/mL must only be diluted in sterile 0.9% m/V sodium chloride solution. Dilution must take place immediately prior to infusion and the solution should be administered as follows:

Iron dose	Product dose	Maximum dilution volume of sterile 0.9% m/V NaCl solution	Minimum infusion time
50 mg	2.5 mL	50 mL	8 minutes
100 mg	5 mL	100 mL	15 minutes
200 mg	10 mL	200 mL	30 minutes

For stability reasons, dilutions to lower Iron Sucrose Injection BP 20 mg/mL concentrations are not permissible.

Intravenous injection: Iron Sucrose Injection BP 20 mg/mL may be administered by slow intravenous injection at a rate of 1 mL undiluted solution per minute and not exceeding 10 mL (200 mg iron) per injection.

Injection into the venous line of a dialysis machine: Iron Sucrose Injection BP 20 mg/mL may be administered during a haemodialysis session directly into the venous line of the dialysis machine under the same conditions as for intravenous injection.

4.3 Contraindications

The use of Iron Sucrose Injection BP 20 mg/mL is contraindicated in the following conditions:

- hypersensitivity to the active substance, Iron Sucrose Injection BP 20 mg/mL or any of its excipients listed in section 6.1;
- known serious hypersensitivity to other parenteral iron products;

- anaemia not caused by iron deficiency;
- evidence of iron overload or hereditary disturbances in utilisation of iron.

4.4 Special warnings and precautions for use

Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic/anaphylactoid reactions. Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes including iron sucrose. There have been reports of hypersensitivity reactions which progressed to Kounis syndrome.

The risk of hypersensitivity reactions is enhanced for patients with known allergies, including drug allergies, and in 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 or rheumatoid arthritis.

Iron Sucrose Injection BP 20 mg/mL 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 injection. If hypersensitivity reactions or signs of intolerance occur during administration, treatment must be stopped immediately. Facilities for cardio-respiratory resuscitation and equipment for handling acute anaphylactic/anaphylactoid reactions should be available, including an injectable 1:1000 adrenaline solution. Additional treatment with antihistamines and/or corticosteroids should be given as appropriate.

In patients with liver dysfunction, parenteral iron should only be administered after careful risk/benefit assessment. Parenteral iron administration should be avoided in patients with hepatic dysfunction where iron overload is a precipitating factor, in particular porphyria cutanea tarda. Careful monitoring of iron status is recommended to avoid iron overload.

Parenteral iron should be used with caution in the case of acute or chronic infection. It is recommended that administration is stopped in patients with bacteraemia. In patients with chronic infection, a risk/benefit evaluation should be performed.

Paravenous leakage must be avoided because leakage at the injection site can lead to pain, inflammation and brown discoloration of the skin.

Iron Sucrose Injection BP 20 mg/mL contains up to 7 mg sodium per mL, equivalent to 0.4% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

As with all parenteral iron preparations, Iron Sucrose Injection BP 20 mg/mL should not be administered concomitantly with oral iron preparations since the absorption of oral iron is reduced. Oral iron therapy should be started at least 5 days after the last injection.

4.6 Fertility, pregnancy and lactation

Pregnancy: There is no data from the use of iron sucrose in pregnant women in the first trimester. Data from use in pregnant women in the second and third trimester showed no safety concerns for the mother or newborn. A careful risk/benefit evaluation is required before use during pregnancy and the product

should not be used during pregnancy unless clearly necessary. Iron deficiency anaemia occurring in the first trimester can in many cases be treated with oral iron. 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 foetus.

Foetal bradycardia may occur following administration of parenteral irons. It is usually transient and a consequence of a hypersensitivity reaction in the mother. The unborn baby should be carefully monitored during intravenous administration of parenteral irons to pregnant women.

Breast-feeding: There is limited information on the excretion of iron in human milk following administration of intravenous iron sucrose. It cannot be excluded that newborns/infants may be exposed to iron derived from Iron Sucrose Injection BP 20 mg/mL via the mother's milk; therefore, the risk/benefit should be assessed.

Fertility: No effects of iron sucrose treatment were observed on fertility and mating performance in rats.

4.7 Effects on ability to drive and use machines

In the case of symptoms of dizziness, confusion or light-headedness following administration of Iron Sucrose Injection BP 20 mg/mL, patients should not drive or use machinery until the symptoms have ceased.

4.8 Undesirable effects

The most commonly reported adverse drug reaction in clinical trials with Iron Sucrose Injection BP 20 mg/mL was dysgeusia, which occurred at a rate of 4.5 events per 100 subjects. The most important serious adverse drug reactions are hypersensitivity reactions, which occurred at a rate of 0.25 events per 100 subjects in clinical trials. Anaphylactoid/anaphylactic reactions were reported only in the post-marketing setting and fatalities have been reported.

The adverse drug reactions reported after administration of Iron Sucrose Injection BP 20 mg/mL in clinical trials and from post-marketing experience are presented below:

System organ class	**Common (≥1/100, <1/10)**	**Uncommon (≥1/1,000, <1/100)**	**Rare (≥1/10,000, <1/1,000)**	**Frequency not known**
Immune system disorders		Hypersensitivity		Anaphylactic/anaphylactoid reactions, angioedema
Nervous system disorders	Dysgeusia	Headache, dizziness, paraesthesia, hypoaesthesia	Syncope, somnolence	Depressed level of consciousness, confusional state, loss of consciousness, anxiety, tremor
Cardiac disorders			Palpitations	Bradycardia, tachycardia, Kounis syndrome
Vascular disorders	Hypotension, hypertension	Flushing, phlebitis		Circulatory collapse, thrombophlebitis
Respiratory, thoracic and mediastinal disorders		Dyspnoea		Bronchospasm
Renal and urinary disorders			Chromaturia	

Gastrointestinal disorders	Nausea	Vomiting, abdominal pain, diarrhoea, constipation		
Skin and subcutaneous tissue disorders		Pruritus, rash		Urticaria, erythema
Musculoskeletal and connective tissue disorders		Muscle spasm, myalgia, arthralgia, pain in extremity, back pain		
General disorders and administration site conditions	Injection/infusion site reaction	Chills, asthenia, fatigue, oedema peripheral, pain	Chest pain, hyperhidrosis, pyrexia	Cold sweat, malaise, pallor, influenza-like illness
Investigations		Alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyltransferase increased, serum ferritin increased	Blood lactate dehydrogenase increased	

Notes:

- Spontaneous reports from the post-marketing setting; estimated as rare.
- The most frequently reported injection/infusion site reactions are injection/infusion site pain, extravasation, irritation, reaction, discolouration, haematoma and pruritus.
- Onset may vary from a few hours to several days.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Overdose can cause iron overload which may manifest itself as haemosiderosis. Overdose should be treated, as deemed necessary by the treating physician, with an iron chelating agent or according to standard medical practice.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-anaemic preparation, iron, parenteral preparation.

ATC code: B03AC.

Mechanism of action: Iron sucrose, the active ingredient of Iron Sucrose Injection BP 20 mg/mL, is composed of a polynuclear iron(III)-hydroxide core surrounded by a large number of non-covalently bound sucrose molecules. The complex has a weight average molecular weight of approximately 43 kDa. The polynuclear iron core has a structure similar to that of the core of the physiological iron storage protein ferritin. The complex is designed to provide, in a controlled manner,

utilisable iron for the iron transport and storage proteins in the body, i.e. transferrin and ferritin.

Following intravenous administration, the polynuclear iron core from the complex is taken up predominantly by the reticuloendothelial system in the liver, spleen and bone marrow. The iron is then used for synthesis of haemoglobin, myoglobin and other iron-containing enzymes, or stored primarily in the liver as ferritin.

Clinical efficacy and safety: In chronic kidney disease, inflammatory bowel disease, postpartum iron deficiency anaemia and pregnancy, clinical studies showed improvement in haemoglobin and/or iron indices following treatment with Iron Sucrose Injection BP 20 mg/mL compared with oral iron in the referenced settings.

5.2 Pharmacokinetic properties

Distribution: The ferrokinetics of iron sucrose labelled with 52Fe and 59Fe were assessed in patients with anaemia and chronic renal failure. In the first 6-8 hours, 52Fe was taken up by the liver, spleen and bone marrow. Following intravenous injection of a single 100 mg iron dose of iron sucrose in healthy volunteers, maximum total serum iron concentrations were attained 10 minutes after injection and had an average concentration of 538 µmol/L. The volume of distribution of the central compartment corresponded well to the volume of plasma, approximately 3 litres.

Biotransformation: Upon injection, sucrose largely dissociates and the polynuclear iron core is mainly taken up by the reticuloendothelial system of the liver, spleen and bone marrow. At 4 weeks after administration, red cell iron utilisation ranged from 59 to 97%.

Elimination: The iron sucrose complex has a weight average molecular weight of approximately 43 kDa, which is sufficiently large to prevent renal elimination. Renal elimination of iron in the first 4 hours after injection of a 100 mg iron dose corresponded to less than 5% of the dose. After 24 hours, total serum iron concentration was reduced to the pre-dose level. Renal elimination of sucrose was about 75% of the administered dose.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity, genotoxicity and toxicity to reproduction and development.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Hydroxide BP

Water for Injection BP

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6. There is the potential for precipitation and/or interaction if mixed with other solutions or medicinal products. The compatibility with containers other than glass, polyethylene and PVC is not known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store in a cool, dry place. Protect from light.

6.5 Nature and contents of container

5 mL amber colour glass ampoule with yellow band.

6.6 Special precautions for disposal and other handling

Ampoules or vials should be visually inspected for sediment and damage before use. Use only those containing a sediment-free and homogeneous solution.

Iron Sucrose Injection BP 20 mg/mL must not be mixed with other medicinal products except sterile 0.9% m/V sodium chloride solution for dilution. For instructions on dilution before administration, see section 4.2. The diluted solution must appear brown and clear.

Each ampoule or vial of Iron Sucrose Injection BP 20 mg/mL is intended for single use only. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Tawwab Pharma Private Limited

Survey no. 622/2/1/4, Himatnagar-Vijapur highway, Himatnagar

India

8. Marketing authorisation number(s)

H2025/CTD10955/24425

9. Date of first authorisation/renewal of the authorisation

12/08/2025

10. Date of revision of the text

12/08/2025