

Venofe[®] (iron sucrose)

Prescribing Information - Ireland

For full prescribing information refer to the Summary of Product Characteristics (SmPC)

Active ingredient: Iron sucrose (20mg/mL)

Presentation: Solution for injection/infusion. Available as a 5mL vial (as 100mg of iron).

Indication: Treatment of iron deficiency 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, and in chronic kidney disease when oral iron preparations are less effective. The diagnosis of iron deficiency must be based on appropriate laboratory tests.

Dosage and Administration: The total cumulative dose of Venofe, equivalent to the total iron deficit (mg), must be individually determined for each patient, based on haemoglobin level and body weight and calculated with the Ganzoni formula. The total single dose must not exceed 200 mg of iron given not more than three times per week.

Administration for intravenous drip infusion:

Venofe must be diluted only in sterile 0.9% m/V sodium chloride solution up to a maximum dilution of 1 mg/ml. For iron doses of 50mg, minimum infusion time is 8 minutes. For doses of 100mg, minimum infusion time is 15 minutes. For doses of 200mg, the minimum administration time is 30 min. **Intravenous injection:** Venofe may be administered by slow intravenous injection at a rate of 1 ml undiluted solution per minute and not exceeding 10 ml Venofe (200 mg iron) per injection.

Administration into dialysis machine: Venofe may be administered during a haemodialysis session directly into the venous line of the dialysis machine under the same conditions as for intravenous injection.

Contraindications: Hypersensitivity to Venofe or any of its excipients. Known serious hypersensitivity to other parenteral iron products. Anaemia not attributed to iron deficiency. Iron overload or disturbances in utilisation of iron.

Special warnings and precautions: Parenterally administered iron preparations can cause potentially fatal anaphylactic/anaphylactoid reactions. The risk is enhanced for patients with known allergies, a history of severe asthma, eczema or other atopic allergy, and in patients with immune or inflammatory conditions. There have been reports of hypersensitivity reactions which progressed to Kounis

syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction).

Venofe should only be administered in the presence of staff trained to manage anaphylactic reactions where full resuscitation facilities are available (including 1:1000 adrenaline solution). Each patient should be observed for 30 minutes following administration. If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. In patients with liver dysfunction, parenteral iron should only be administered after careful risk/benefit assessment. Careful monitoring of iron status is recommended to avoid iron overload. Parenteral iron must be used with caution in case of acute or chronic infection, asthma, eczema or atopic allergies. It is recommended that treatment with Venofe is stopped in patients with ongoing bacteraemia. In patients with chronic infection a benefit/risk evaluation has to be performed. Caution should be exercised to avoid paravenous leakage when administering Venofe.

Special populations: The use of Venofe has not been studied in children. A careful risk/benefit evaluation is required before use during pregnancy. Venofe should not be used during pregnancy unless clearly necessary and should be confined to the second and third trimester. Foetal bradycardia may occur during administration of parenteral irons, as a consequence of hypersensitivity. The unborn baby should be carefully monitored during administration to pregnant women.

Undesirable effects Common ($\geq 1/100$ to $< 1/10$): Dysgeusia, hypotension, hypertension, nausea and injection/infusion site reactions. Frequency not known: Anaphylactoid/anaphylactic reactions and Kounis syndrome. Please consult the SmPC in relation to other undesirable effects.

Legal category: POM

MA Number: PA 949/001/002

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MA Holder: Vifor France, 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, France

Venofe[®] is a registered trademark

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Additional information is available on request

Adverse events should be reported. Reporting forms and information can be found at

<http://www.hpra.ie/homepage/about-us/report-an-issue>

Adverse events should also be reported to Vifor Pharma UK Ltd. Tel: +44 1276 853633

Email: medicalinfo_UK@viforpharma.com