Date : 17.02.2022
Export Philippines

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IRON SUCROSE

℞ **INOFAR**

20mg/ mL (100 mg/ 5 mL)
Solution for Intravenous Infusion
Anti-Anemic

Product Description:
A deep brown coloured liquid, free from any extraneous matter

FORMULATION:
Each mL contains:
Iron Sucrose equivalent to elemental Iron 20 mg

PHARMACOKINETICS:
Iron Sucrose is rapidly cleared from the plasma after intravenous injection with a terminal half-life of about 6 hours. A competitive exchange of iron takes place from the iron sucrose complex to the iron-binding protein transferring. About 5% of a dose is eliminated via the kidneys in the first 4 hours after a dose.

INDICATION:
It is used as a source of iron for iron deficiency anemia.

DOSAGE AND ADMINISTRATION:
It is given when oral iron therapy is ineffective or impractical, by slow intravenous injection, or intravenous infusion; when used in haemodialysis patients, it may be given into the venous limb of the dialyser. The dose is calculated according to body-weight and iron deficit. In the UK the cumulative dose is given in single doses of 100 mg of iron not more than three times weekly; if rapid delivery is required, the dose may be increased up to 200 mg not more than three times weekly. The dose may be given undiluted at a rate of 20 mg/minute, after a test dose of 20 mg of iron has been given over 1 to 2 minutes. Alternatively, 100 mg is diluted in a maximum of 100 mL of sodium chloride 0.9% and the first 25 mg given as a test dose over 15 minutes; the remaining portion is given at a rate not exceeding 50 mL per 15 minutes.
In the USA, a similar dose is given for haemodialysis patients receiving supplemental erythropoietin therapy, to a total cumulative dose of 1 g. For peritoneal dialysis patients on erythropoietin, two infusions of 300 mg over 1.5 hours are given 14 days apart, followed by an infusion of 400 mg over 2.5 hours 14 days later. The doses are diluted in a maximum of 250 mL of sodium chloride 0.9%. For patients not on dialysis, a total cumulative dose of 1 g is given over a 14 day period, as a 200 mg slow undiluted intravenous injection over 2 to 5 minutes on 5 separate occasions within this time. Iron sucrose has also been given orally.

ADVERSE EFFECT:
Iron Sucrose: All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome when using Iron Sucrose:
Diarrhea; dizziness; headache; muscle cramps; nausea; taste changes; vomiting.
Seek medical attention right away if any of this SEVERE SIDE EFFECTS OCCUR WHEN USING Iron sucrose:
Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face lips, or tongue; unusual hoarseness); burning or pain at the injection site; burning, numbness, or tingling; chest pain; fainting; loss of consciousness; severe or persistent dizziness, headache, or light-headedness; seizures; shortness of breath; swelling of the hands, ankles, or feet.

Reporting of Suspected Adverse Reactions:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph. Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

INTERACTION:
Iron sucrose should not be administered with oral iron preparations since the absorption of oral iron is reduced. Therefore, oral iron therapy should be started at least 5 days after the last injection of Iron Sucrose.

PRECAUTIONS:
Iron sucrose injection is strongly alkaline and must not be given subcutaneously or intramuscularly.

CONTRAINDICATIONS:
UK Licensed drug information contraindicates its use in patients with a history of asthma, eczema, anaphylaxis, or other allergic disorders.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:
Store at temperature not exceeding 30°C.

AVAILABILITY:
USP Type I glass amber ampoule x 5mL (Box of 2 ampoules)

FDA Reg. No: DRP-4634
Date of Renewal Authorization : 12 December 2017
Date of Revision of Package Insert : 16 February 2022

Manufactured by:
ARISTOPHARMA LTD.
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