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For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

AKUROSE

POM

Iron Sucrose Injection USP 20mg/ml

COMPOSITION

Each ml contains:

Iron Sucrose	
eq. to Elemental Iron	20 mg
Water for Injection USP	q.s.

PHARMACEUTICAL FORM

Injection

THERAPEUTIC INDICATIONS

Akurose is indicated for the treatment of iron deficiency in the following indications:

- where there is a clinical need to deliver iron rapidly to iron stores,
- in patients who cannot tolerate oral iron therapy or who are non-compliant,
- in active inflammatory bowel disease where oral iron preparations are ineffective.

DOSAGE AND ADMINISTRATION

Administration: Akurose must only be administered by the intravenous route. This may be by a slow intravenous injection or by an intravenous drip infusion.

Akurose must not be used for intramuscular injection.

Adults and the elderly: The total cumulative dose of Akurose, equivalent to the total iron deficit (mg), is determined by the haemoglobin level and body weight. The dose for Akurose must be individually determined for each patient according to the total iron deficit calculated with the following formula:

Total iron deficit(mg) = Body weight(kg) * (Target Hb – Actual Hb)[g/l] * 0.24 + Depot iron(mg)

Dosage: The total single dose must not exceed 200 mg of iron given not more than three times per week. If the total necessary dose exceeds the maximum allowed single dose, then the administration has to be split.

Children: The use of Akurose has not been adequately studied in children and, therefore, Akurose is not recommended for use in children.

Intravenous drip infusion: Akurose must be diluted only in sterile 0.9% m/V sodium chloride solution:

- 2.5 ml Akurose (50 mg iron)
  in max. 50 ml sterile 0.9% m/V sodium chloride solution
- 5 ml Akurose (100 mg iron)
  in max. 100 ml sterile 0.9% m/V sodium chloride solution
- 10 ml Akurose (200 mg iron)
  in max. 200 ml sterile 0.9% m/V sodium chloride solution

For stability reasons, dilutions to lower Akurose concentrations are not permissible.
Dilution must take place immediately prior to infusion and the solution should be administered as follows:

- 100 mg iron (5 ml Akurose) in at least 15 minutes
- 200 mg iron (10 ml Akurose) in at least 30 minutes

Intravenous injection: Akurose may be administered by slow intravenous injection at a rate of 1 ml undiluted solution per minute and not exceeding 10 ml Akurose (200 mg iron) per injection.

Injection into dialyser: Akurose may be administered during a haemodialysis session directly into the venous limb of the dialyser under the same procedures as those outlined for intravenous injection.

CONTRAINDICATIONS

The use of Akurose is contraindicated in cases of:

- Hypersensitivity to the active substance
- Known serious hypersensitivity to other parenteral iron products
- Anaemias not attributable to iron deficiency
- Iron overload or disturbances in utilisation of iron

SPECIAL WARNINGS AND PRECAUTIONS

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.

The risk is enhanced for patients with known allergies including drug allergies, including 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, rheumatoid arthritis).

Akurose should only be administered when staff trained to evaluate and manage anaphylactic reactions is 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 Akurose injection. If hypersensitivity reactions or signs of intolerance occur during administration, the 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 (PCT). Careful monitoring of iron status is recommended to avoid iron overload.

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Parenteral iron must be used with caution in case of acute or chronic infection. It is recommended that the administration of iron sucrose is stopped in patients with ongoing bacteraemia. In patients with chronic infection a risk/benefit evaluation has to be performed, taking into account the suppression of erythropoiesis.

Hypotensive episodes may occur if the injection is administered too rapidly. Allergic reactions, sometimes involving arthralgia, have been more commonly observed when the recommended dose is exceeded.

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

DRUG INTERACTIONS

As with all parenteral iron preparations, Akurose should not be administered concomitantly 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 Akurose.

PREGNANCY AND LACTATION

Pregnancy

There are no adequate and well-controlled trials of Akurose in pregnant women. A careful risk/benefit evaluation is therefore required before use during pregnancy and Akurose should not be used during pregnancy unless clearly necessary.

Iron deficiency anaemia occurring in the first trimester of pregnancy can in many cases be treated with oral iron. Treatment with Akurose should be confined to second and third trimester if the benefit is judged to outweigh the potential risk for both the mother and the foetus.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Data on a limited number of exposed human pregnancies indicated no adverse effects of Akurose on pregnancy or on the health of the foetus/newborn child.

Breastfeeding

Non metabolised Akurose is unlikely to pass into the mother's milk. No well-controlled clinical studies are available to date. Animal studies do not indicate direct or indirect harmful effects to the nursing child.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

In the case of symptoms of dizziness, confusion or light headedness following the administration of Akurose, patients should not drive or use machinery until the symptoms have ceased

UNDESIRABLE EFFECTS

Transient taste perversions (in particular metallic taste), Hypotension, Tachycardia, Palpitations, Bronchospasm, Dyspnoea, Nausea; Vomiting, Abdominal pain, Diarrhoea, Pruritus, Urticaria, Rash, Exanthema, Erythema, Muscle cramps, Myalgia, Fever, Shivering, Flushing, Chest pain, Tightness, Burning, Swelling.

OVERDOSAGE

Overdosage can cause acute iron overloading which may manifest itself as haemosiderosis. Overdosage should be treated, if required, with an iron chelating agent.

PHARMACODYNAMIC PROPERTIES

Iron sucrose is a dark brown, slightly viscous sterile liquid complex of ferric hydroxide and sucrose for intravenous or intramuscular use. After iron sucrose is injected, the circulating iron sucrose is removed from the plasma by cells of the reticuloendothelial system, which split the complex into its components of iron and sucrose. The iron is immediately bound to the available protein moieties to form hemosiderin or ferritin, the physiological forms of iron, or to a lesser extent to transferrin. This iron which is subject to physiological control replenishes hemoglobin and depleted iron stores.

PHARMACOKINETIC PROPERTIES

Following intravenous injection of a single dose of Akurose containing 100 mg iron in healthy volunteers, maximum iron levels, averaging 538 µmol/l, were obtained 10 minutes after injection. The volume of distribution of the central compartment corresponded well to the volume of plasma.

The iron injected was rapidly cleared from the plasma, the terminal half-life being approx. 6 h. The volume of distribution at steady state was about 8 litres, indicating a low iron distribution in the body fluid. Due to the lower stability of iron sucrose in comparison to transferrin, a competitive exchange of iron to transferrin was observed. This resulted in iron transport of approx. 31 mg iron/24 h.

Renal elimination of iron, occurring in the first 4 h after injection, corresponds to less than 5% of the total body clearance. After 24 h the plasma levels of iron were reduced to the pre-dose iron level and about 75% of the dosage of sucrose was excreted.

STORAGE CONDITIONS

Store below 30°C, in a dry & dark place. Do not freeze.
Keep all medicines out of reach of children.

PRESENATION

AKUROSE Tray of 5x5 ml Ampoules packed in Mono Carton along with Insert.

Product from

Unosource Pharma Ltd.

Manufactured by:
Akums Drugs & Pharmaceuticals Ltd.
Plot No. 2,3,4 & 5, Sector-6B, I.I.E., SIDCUL,
Ranipur, Haridwar-249 403, Uttarakhand, INDIA.

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