NOVARTIS

DESFERAL®

(desferrioxamine)

Basic Succinct Statement

CODE: BSS RD 04 Apr 18; APPR 18 Feb 20

This material is only meant for Healthcare Professionals

DESFERAL®

Important Note: Before prescribing, please read full prescribing information.

Presentation: Deferoxamine mesylate (also known as desferrioxamine methane sulphonate: vials containing 500 mg powder for solution for injection.

Indications: ♦Monotherapy iron chelation treatment for chronic iron overload (e.g. transfusional haemosiderosis, as seen in thalassaemia major, sideroblastic anaemia, autoimmune haemolytic anaemia, and other chronic anaemias; idiopathic haemochromatosis in patients in whom concomitant disorders preclude phlebotomy; iron overload associated with porphyria cutanea tarda in patients unable to tolerate phlebotomy). ♦Acute iron poisoning. ♦Chronic aluminium overload in renal patients on maintenance dialysis (e.g. with aluminium-related bone disease, dialysis encephalopathy or aluminium-related anaemia). ♦Test for iron or aluminium overload.

Dosage and administration: The dosage and mode of administration should be determined individually, depending on the indication and the severity of the condition. Chronic iron overload: 20 to 60 mg/kg bodyweight daily; acute iron poisoning: up to 80 mg/kg/day ; chronic aluminium overload: 5 mg/kg bodyweight once weekly ; test for iron overload: 500 mg ; infusion test for aluminium overload: 5 mg/kg bodyweight .

Contraindications: Known hypersensitivity to the active substance, except where successful desensitization makes treatment possible.

Warnings and precautions: ♦Rapid intravenous infusion. ♦Vision and hearing impairment: ophthalmological and audiological tests before and during treatment. ♦Caution when severe renal failure. Isolated reports of acute renal failure. Monitoring patients for changes in renal function. ♦Growth retardation in paediatrics: monitoring of pediatric patients for body weight and longitudinal growth every 3 months. ♦Acute respiratory distress syndrome following high IV doses ♦Increases susceptibility to infections with *Yersinia enterocolitica* and *Yersinia pseudotuberculosis*. If such cases, discontinue Desferal until the infection has been successfully treated. ♦Rare cases of mucormycosis, some with a fatal outcome: If any of the suspected signs or symptoms occur discontinue Desferal and start antifungal treatment immediately ♦Cardiac impairment with high doses of vitamin C (more than 500mg daily) in patients with severe chornic iron overload. In patients with severe chronic iron overload, impairment of cardiac function occurred following concomitant treatment with Desferal and high doses of vitamin C. Cardiac dysfunction was reversible upon discontinuation of vitamin C ♦In patients with aluminium-related encephalopathy, high doses may exacerbate neurological dysfunction (seizure), hypocalcemia and aggravation of hyperparathyroidism in patients treated for aluminium overload. ♦Concentration of Desferal solution should not be higher than 95mg/mL when given subcutaneously. ♦Excretion of the iron complex may cause reddish-brown urine discoloration. ♦Should not be used during pregnancy unless clearly necessary. ♦Not recommended when breast-feeding.

Interactions: Prochlorperazine, vitamin C, gallium-67-imaging.

Adverse reactions: ♦**Very common**: Arthralgia, myalgia, injection site reaction injection site pain, swelling, injection site extravasation, injection site erythema, injection site pruritus, injection site scab. ♦**Common**: headache, urticaria, nausea or pyrexia, growth retardation, bone disorder, metaphyseal dysplasia. ♦**Uncommon**: Deafness, tinnitus, asthma, vomiting, abdominal pain, injection site vesicles, injection site oedema. ♦**Rare**: Mucormycosis, loss of vision, retinal degeneration, optic neuritis, cataract, visual acuity reduced, vision blurred, night blindness,

chromatopsia, corneal opacity, hypotension, tachycardia and shock, increased transaminases (causality with the drug not established) ♦ **Very rare**: Gastroenteritis Yersinia, blood disorder (incl. thrombocytopenia, leukopenia), anaphylactic shock/reaction, angioedema, neurological disturbances including dizziness, encephalopathy*, neuropathy peripheral, paresthesia, acute respiratory distress syndrome, lung infiltration, diarrhoea, rash generalised. ♦ **Not known frequency:** Seizures, hypocalcaemia and aggravation of hyperparathyroidism in dialysed patients treated with aluminum overload muscle spasms, acute kidney failure, renal tubular disorder, blood creatinine increased, excretion of the iron complex may cause reddish-brown urine discoloration.

*****precipitation or exacerbation of aluminum-related dialysis encephalopathy