NOVARTIS

SIMULECT® (basiliximab)

Powder and solvent for solution for infusion or injection

Basic Succinct Statement

Code: BSS RD 13 JAN 2014; APPR 10 DEC 2015

This material is only meant for Healthcare Professionals

SIMULECT®

Important note: Before prescribing, consult full prescribing information.

Presentation: Basiliximab as powder for intravenous injection or infusion: vials of 20 mg, with an ampoule of 5 mL of water for injection for reconstitution.

Indication: Prophylaxis of acute organ rejection in *de novo* renal transplantation in adults and children, to be used concomitantly with ciclosporin for microemulsion- and corticosteroid-based immunosuppression, or in a triple therapy regimen with ciclosporin for microemulsion, corticosteroids and either azathioprine or mycophenolate mofetil.

Dosage: ♦Two doses, the first within 2 hours before transplantation surgery, the second 4 days after transplantation. ♦**For adults, and children weighing 35 kg or more**: 20 mg basiliximab per dose. ♦**For children weighing less than 35 kg**: 10 mg basiliximab per dose.

Contraindications: Hypersensitivity to basiliximab or to other components of the formulation.

Warnings/Precautions: ♦Simulect should be prescribed only by physicians experienced in use of immunosuppressive therapy after organ transplantation. ♦If severe hypersensitivity/anaphylactoid type reactions occur, therapy with Simulect should be permanently discontinued and no further dose should be administered. Caution should be exercized when patients previously given Simulect are re-exposed to a subsequent course of therapy with this medicine. ♦Transplant patients receiving immunosuppressive regimens involving combinations with or without Simulect are at increased risk of developing lymphoproliferative disorders (LPDs) (such as lymphoma) and opportunistic infections (such as cytomegalovirus, CMV). ♦Live vaccines are not recommended for immunosuppressed patients. Inactivated vaccines may be administered to immunosuppressed patients; however, response to the vaccine may depend on the degree of the immunosuppression.

♦**Pregnancy**. Should not be given to pregnant women except in cases where the potential benefit for the mother outweighs the potential risk for the fetus. Adequate contraception for 4 months after the last dose.

♦**Breast-feeding**: Women receiving Simulect should not breast-feed for 4 months after the last dose.

Interactions: ♦Combined use of Simulect with ciclosporin for microemulsion, corticosteroids, azathioprine and mycophenolate mofetil did not increase the potential for over-immunosuppression. ♦Other medications have been administered in clinical trials without any incremental adverse reactions; e.g. systemic antiviral, antibacterial and antimycotic agents, analgesics, antihypertensives such as beta-blockers or calcium channel blockers, and diuretics.

Adverse reactions: ♦Hypersensitivity/anaphylactoid reactions such as rash, urticaria, pruritus, sneezing, wheezing, bronchospasm, dyspnoea, pulmonary edema, cardiac failure, hypotension, tachycardia, respiratory failure and capillary leak syndrome as well as cytokine release syndrome have been reported during post marketing experience with Simulect. ♦The

most commonly reported (>20%) events following dual or triple therapy in adults were constipation, urinary tract infection, pain, nausea, peripheral edema, hypertension, anaemia, headache, hyperkalemia, hypercholesterolemia, postoperative wound complication, weight increase, increase in blood creatinine, hypophosphatemia, diarrhea and upper respiratory tract infection. ♦The most commonly reported (>20%) events following dual therapy in children were urinary tract infection, hypertrichosis, rhinitis, pyrexia, hypertension, upper respiratory tract infection and viral infection, constipation and sepsis.