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NOVARTIS

Important Prescribing Information

October 6, 2000

Dear Healthcare Provider:

We are writing to inform you of post marketing reports of seventeen cases of severe acute hypersensitivity reactions, including anaphylaxis, occurring in patients following the administration of Simulect (basiliximab). The onset of these reactions occurred within 24 hours following initial exposure and/or following re-exposure to Simulect. Therefore, we recommend that medications for the treatment of severe hypersensitivity reactions, including anaphylaxis, be available for immediate use and that the second dose of Simulect be withheld if a hypersensitivity reaction occurs. The ***Warnings, Dosage and Administration and Adverse Reactions*** sections of the labeling for Simulect have been revised to reflect this new information. Enclosed is the revised labeling for Simulect; presented below are the amended sections of the labeling.

WARNINGS

Hypersensitivity

Severe acute (onset within 24 hours) hypersensitivity reactions including anaphylaxis have been observed both on initial exposure to Simulect® and/or following re-exposure after several months. These reactions may include hypotension, tachycardia, cardiac failure, dyspnea, wheezing, bronchospasm, pulmonary edema, respiratory failure, urticaria, rash, pruritus, and/or sneezing. If a severe hypersensitivity reaction occurs, therapy with Simulect® should be permanently discontinued. Medications for the treatment of severe hypersensitivity reactions including anaphylaxis should be available for immediate use. Patients previously administered Simulect® should only be re-exposed to a subsequent course of therapy with extreme caution. The potential risks of such re-administration, specifically those associated with immunosuppression, are not known.

DOSAGE AND ADMINISTRATION

Simulect® should only be administered once it has been determined that the patient will receive the graft and concomitant immunosuppression. Patients previously administered Simulect® should only be re-exposed to a subsequent course of therapy with extreme caution.

Adult*:* In adult patients, the recommended regimen is two doses of 20 mg each. The first 20 mg dose should be given within 2 hours prior to transplantation surgery. The recommended second 20 mg dose should be given 4 days after transplantation. The second dose should be withheld if complications such as severe hypersensitivity reactions to Simulect® or graft loss occur.

Pediatric*:* For children and adolescents from 2 up to 15 years of age, the recommended regimen is two doses of 12 mg/m^2 each, up to a maximum of 20 mg/dose. The first dose should be given within 2 hours prior to transplantation surgery. The second dose should be given 4 days after transplantation. The second dose should be withheld if complications such as severe hypersensitivity reactions to Simulect® or graft loss occur.

ADVERSE REACTIONS

Post Marketing Experience

Severe acute hypersensitivity reactions including anaphylaxis characterized by hypotension, tachycardia, cardiac failure, dyspnea, wheezing, bronchospasm, pulmonary edema, respiratory failure, urticaria, rash, pruritus, and/or sneezing, as well as capillary leak syndrome and cytokine release syndrome, have been reported during post-marketing experience with Simulect®.

Novartis is committed to providing you with the most current product information available for the management of patients receiving Simulect. You can further our understanding of adverse events by reporting them.

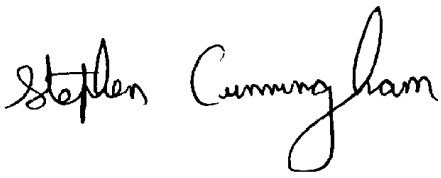
Healthcare professionals should report all serious adverse events suspected to be associated with the use of Simulect to Novartis Pharmaceuticals Corporation, 59 Route 10, East Hanover, New Jersey 07936 by phone (888) NOW-NOVARTIS or (888-669-6682) or the internet at http://www.novartis.com.

Alternatively, this information may be reported to FDA's MedWatch Reporting System by phone at 1-800-FDA-1088, by facsimile 1-800-FDA-0178, by mail using the Form 3500 at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20857, or online at http://www.accessdata.FDA.gov/scripts/medwatch.

Please see the enclosed revised package insert for complete prescribing information.

Sincerely,

Alan L. Bess, MD
Vice President
Clinical Safety & Epidemiology



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