September 2009

IMPORTANT DRUG INFORMATION

Dear Healthcare Professional:

Roche would like to advise you that production of ZENAPAX® (daclizumab) Sterile Concentrate for Injection has been discontinued for the United States market. The existing supply of ZENAPAX is expected to be depleted by January 2010 based on current demand. The last lots of ZENAPAX for the United States market will expire in 2011.

This decision has been taken in view of available alternative treatments and the diminishing market demand for ZENAPAX and is not due to any safety issue.

ZENAPAX is indicated for the prophylaxis of acute organ rejection in patients receiving renal transplants. It is used as part of an immunosuppressive regimen that includes cyclosporine and corticosteroids. The efficacy of ZENAPAX for the prophylaxis of acute rejection in recipients of other solid organ allografts has not been demonstrated.

Based on clinical trials, the standard course of ZENAPAX therapy at the recommended dose of 1.0 mg/kg is five doses. The first dose should be given no more than 24 hours before transplantation. The four remaining doses should be given at intervals of 14 days.

Important Prescribing and Safety Information:

WARNING: Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should prescribe ZENAPAX. The physician responsible for ZENAPAX administration should have complete information requisite for the follow-up of the patient. ZENAPAX should only be administered by healthcare personnel trained in the administration of the drug who have available adequate laboratory and supportive medical resources.

Severe, acute (onset within 24 hours) hypersensitivity reactions including anaphylaxis have been observed both on initial exposure to ZENAPAX and following re-exposure. If a severe hypersensitivity reaction occurs, therapy with ZENAPAX should be permanently discontinued. Medications for the treatment of severe hypersensitivity reactions including anaphylaxis should be available for immediate use. Patients previously administered ZENAPAX should only be re-exposed to a subsequent course of therapy with caution. The potential risks of such re-administration, specifically those associated with immunosuppression, are not known.

ZENAPAX is contraindicated in patients with known hypersensitivity to daclizumab or to any components of this product.

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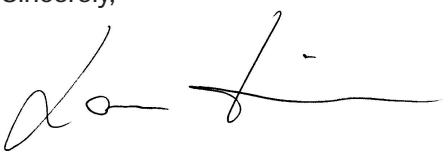
While the incidence of lymphoproliferative disorders and opportunistic infections in the limited clinical trial experience was no higher in patients treated with ZENAPAX compared with placebo-treated patients, patients on immunosuppressive therapy are at increased risk for developing lymphoproliferative disorders and opportunistic infections and should be monitored accordingly.

In clinical trials, the most frequently reported adverse events were GI disorders (eg, constipation, nausea, diarrhea, and vomiting): ZENAPAX-treated patients, 67%; placebo-treated patients, 68%. Cellulitis and wound infections occurred in 8.4% of ZENAPAX-treated patients and in 4.1% of placebo-treated patients.

The use of ZENAPAX was associated with a higher incidence of mortality when compared to placebo in a large randomized controlled study of patients receiving cardiac transplants. Some, but not all, of the increase in mortality appeared related to a higher incidence of severe infections. Concomitant use of anti-lymphocyte antibody therapy may also be a factor in some fatal infections.

Enclosed you will find the complete Prescribing Information for ZENAPAX® (daclizumab) Sterile Concentrate for Injection. If you have any questions or require additional information concerning the discontinuation of ZENAPAX, please contact the Roche Pharmaceuticals Service Center at (800) 526-6367.

Sincerely,



Lars E. Birgerson, MD, PhD
Vice President, US Medical Affairs

Enclosure: Complete Prescribing Information for ZENAPAX® (daclizumab) Sterile Concentrate for Injection

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