Novartis Pharmaceuticals Corporation
East Hanover, New Jersey

April 18, 2005

IMPORTANT DRUG WARNING

Dear Health Care Provider:

Novartis Pharmaceuticals Corporation would like to inform you about important changes to the WARNINGS and PRECAUTIONS sections of the prescribing information for TRILEPTAL® (oxcarbazepine) tablets and oral suspension. TRILEPTAL is indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults and children ages 4-16 years with epilepsy.

The updated WARNINGS section calls your attention to serious dermatological reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) that have been reported in both children and adults in association with Trileptal use. The PRECAUTIONS section has been updated to include language regarding multi-organ hypersensitivity reactions that have been reported in association with Trileptal use.

In order to communicate this important postmarketing information to healthcare professionals, the following information regarding serious dermatological reactions has been added to the WARNINGS section of the prescribing information:

WARNINGS

Serious Dermatological Reactions

Serious dermatological reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in both children and adults in association with Trileptal use. The median time of onset for reported cases was 19 days. Such serious skin reactions may be life-threatening, and some patients have required hospitalization with very rare reports of fatal outcome. Recurrence of the serious skin reactions following re-challenge with Trileptal has also been reported.

The reporting rate of TEN and SJS associated with Trileptal use, which is generally accepted to be an underestimate due to underreporting, exceeds the background incidence rate estimates by a factor of 3 to 10 fold. Estimates of the background incidence rate for these serious skin reactions in the general population range between 0.5 to 6 cases per million person years. Therefore, if a patient develops a skin reaction while taking Trileptal, consideration should be given to discontinuing Trileptal use and prescribing another anti-epileptic medication.

The following information regarding multi-organ hypersensitivity reactions has been inserted to the PRECAUTIONS section of the Trileptal prescribing information:

PRECAUTIONS

Multi-organ hypersensitivity

Multi-organ hypersensitivity reactions have occurred in close temporal association (median time to detection 13 days: range 4-60) to the initiation of Trileptal therapy in adult and pediatric patients. Although there have been a limited number of reports, many of these cases resulted in hospitalization and some were considered life threatening. Signs and symptoms of this disorder were diverse; however, patients typically, although not exclusively, presented with fever and rash associated with other organ system involvement. Other associated manifestations included lymphadenopathy, hepatitis, liver function test abnormalities, hematological abnormalities (e.g., eosinophilia, thrombocytopenia, neutropenia), pruritis, nephritis, oliguria, hepato-renal syndrome, arthralgia and asthenia. Because the disorder is variable in its expression, other organ system symptoms and signs, not noted here, may occur. If this reaction is suspected, Trileptal should be discontinued and an alternative treatment started. Although there are no case reports to indicate cross sensitivity with other drugs that produce this syndrome, the experience amongst drugs associated with multi-organ hypersensitivity would indicate this to be a possibility (see WARNINGS, Patients with a Past History of Hypersensitivity Reaction to Carbamazepine subsection).

Additional language regarding serious dermatological reactions and multi-organ hypersensitivity have been inserted under the Information for Patients heading of the PRECAUTIONS section of the prescribing information and are related to these important changes to the WARNINGS and PRECAUTIONS sections of the prescribing information.

Novartis is committed to the safety and well being of all patients receiving TRILEPTAL (oxcarbazepine) tablets and oral suspension. If you become aware of any case(s) of the events described above, in patients treated with TRILEPTAL, please report the event promptly. You may contact Novartis by phone at 1-800-882-6577 or by Fax 1-888-299-4565, or the FDA MedWatch program, by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, or by mail to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20857, or by the Internet at https://www.accessdata.fda.gov/scripts/medwatch/.

If you have any questions, please contact Novartis Medical Information & Communications at 1-800-524-0264.

Please see the revised full prescribing information for TRILEPTAL enclosed with this letter.

Sincerely,

Alan L. Bess, M.D.
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Clinical Safety & Epidemiology

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