IMPORTANT DRUG SAFETY INFORMATION

NOVARTIS

Subject: Association of TRILEPTAL (oxcarbazapine) with life-threatening dermatological reactions and multi-organ hypersensitivity

April 27, 2005

Dear Health Care Professional:

Novartis Pharmaceuticals Canada Inc., following discussion with Health Canada, would like to inform you about new safety information concerning the risk of serious dermatological reactions, including Stevens Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN), as well as multi-organ hypersensitivity reactions in both children and adults, associated with the use of TRILEPTAL* (oxcarbazepine).
The WARNINGS AND PRECAUTIONS section of the TRILEPTAL Product Monograph is being revised as appropriate. Please carefully review the information noted below:

Life-threatening 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 the use of TRILEPTAL.**
- **The reporting rate of SJS and TEN with use of TRILEPTAL currently exceeds the background incidence rate estimates by a factor of 3-10 fold. Some patients have required hospitalization with very rare reports of fatal outcome. Most cases occurred within the first month. 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.**
- **If a patient develops any skin reaction while taking TRILEPTAL, consideration should be given to discontinuing Trileptal use and prescribing another anti-epileptic. A diagnosis of SJS or TEN requires immediate discontinuation of TRILEPTAL.**

Multi-Organ Hypersensitivity

- **A limited number of cases of multi-organ hypersensitivity reactions have been reported in both children and adults in association with the use of TRILEPTAL. 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 various organ system abnormalities, including liver, kidney and hematological. Other organ symptoms and signs may occur.**
- **If this reaction is suspected, TRILEPTAL should be discontinued immediately and an alternative treatment started.**

Cross-Sensitivity with Carbamazapine:

- **Approximately 25-30% of patients who have had hypersensitivity reactions to carbamazapine will experience hypersensitivity reactions with TRILEPTAL. Hypersensitivity reactions may also occur in patients without a history of hypersensitivity to carbamazapine**.

TRILEPTAL is indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults and children ages 6-16 with epilepsy

The Consumer Information section of the TRILEPTAL Product Monograph is being updated accordingly.

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 to:

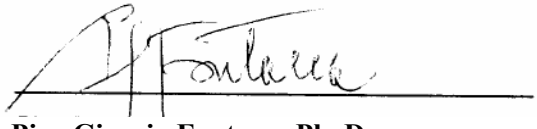
Novartis Pharmaceuticals Canada Inc.
385 Bouchard blvd,
Dorval, (QC) H9S 1A9
Phone:1-800-363-8883 (Medical Information)

Any suspected adverse reaction can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
OTTAWA, Ontario, K1A 0K9
Tel: (613) 957-0337 or
Fax: (613) 957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free: Tel: 866 234-2345
Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

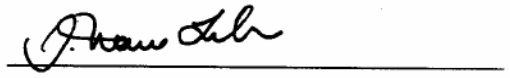
The AR Reporting Form (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adverse_e.html) and the AR Guidelines (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr_guideline_e.html) can be found on the Therapeutic Products Directorate web site or in The Canadian Compendium of Pharmaceuticals and Specialties.

Should you have any questions or require additional information regarding the use of TRILEPTAL (oxcarbazepine), please contact Novartis Pharmaceuticals Canada Inc., Medical Information at 1-800-363-8883 from 8:30 AM to 4:30 PM Monday to Friday Eastern Standard Time.

Sincerely,



Pier-Giorgio Fontana, Ph. D.
Vice-President, Regulatory Affairs



Jean-Marie Leclerc, M.D., FRCP (c)
Vice-President, Clinical and Regulatory Affairs

*TRILEPTAL (oxcarbazepine) is a registered trademark.