JANSSEN-ORTHO Inc.

Subject: Association of TOPAMAX* (topiramate) with Acute Myopia and Secondary Angle Closure Glaucoma

September 10, 2001

Dear Healthcare Professional:

We have updated the prescribing information for TOPAMAX to provide new information about an ocular syndrome that has occurred in patients receiving topiramate. This syndrome is characterized by acute myopia and secondary angle closure glaucoma. This information is based on post-marketing experience in more than 825,000 patients. Clinicians are advised to carefully review the WARNINGS and PRECAUTIONS sections of the revised Prescribing Information and the revised Information to the Consumer/Parent. Highlighted documents have been enclosed for your review. Please insert this information into your copy of the CPS and use when prescribing and dispensing TOPAMAX. Additionally, it is important to discuss the new information contained in the Information to the Patient with your patients.

As of August 2001 there have been approximately 23 reported cases: 22 in adults and at least one pediatric case. One of these cases was reported in Canada. It is generally recognized that post-marketing data are subject to substantial under-reporting.

Symptoms have typically occurred within the first month of therapy, with patients reporting an acute onset of decreased visual acuity and/or ocular pain. Eye examination revealed myopia, redness, shallowing of the anterior chamber and elevated ocular pressure, with or without pupil dilatation. Supraciliary effusion may displace the lens and iris anteriorly, secondarily causing angle closure glaucoma.

If patients develop this syndrome, the primary treatment to reverse symptoms is discontinuation of TOPAMAX as rapidly as possible, according to the judgement of the treating physician. Other measures, in conjunction with discontinuation of TOPAMAX, may be helpful.

The following has been added to the TOPAMAX Prescribing Information:

Under WARNINGS

Acute Myopia and Secondary Angle Closure Glaucoma

A syndrome consisting of acute myopia associated with secondary angle closure glaucoma has been reported in patients receiving TOPAMAX. Symptoms include acute onset of decreased visual acuity and/or ocular pain. Ophthalmologic findings can include myopia, anterior chamber shallowing, ocular hyperemia (redness) and increased intraocular pressure. Mydriasis may or may not be present. This syndrome may be associated with supraciliary effusion resulting in anterior displacement of the lens and iris, with secondary angle closure glaucoma. Symptoms typically occur within a few days to 1 month of initiating TOPAMAX therapy. In contrast to primary narrow angle glaucoma, which is rare under 40 years of age, secondary angle closure glaucoma associated with topiramate has been reported in pediatric patients as well as adults. The primary treatment to reverse symptoms is discontinuation of TOPAMAX as rapidly as possible, according to the judgement of the treating physician. Other measures, in conjunction with discontinuation of TOPAMAX, may be helpful (see PRECAUTIONS and Post-Marketing Adverse Reactions).

In all cases of acute visual blurring and/or painful/red eye(s), immediate consultation with an ophthalmologist is recommended.

Elevated intraocular pressure of any etiology, if left untreated, can lead to serious sequelae including permanent vision loss.

19 Green Belt Drive, Toronto, Ontario, Canada M3C 1L9

Under PRECAUTIONS

Information for Patients

Acute Myopia and Secondary Angle Closure Glaucoma

Patients taking TOPAMAX should be told to immediately contact their doctor and/or go to the Emergency Room if they/their child experience(s) sudden worsening of vision, blurred vision or painful/red eye(s).

The following has been added to the TOPAMAX Information for the Consumer/Parent:

Contact your doctor immediately or go to the Emergency Room if you/your child experience(s) sudden worsening of vision, blurred vision or painful/red eye(s).

The identification, characterization, and management of drug-related adverse events are dependent on the active participation of healthcare professionals in adverse drug reaction reporting programmes. Your professional commitment in this regard has an important role in protecting the well-being of your patients by contributing to early signal detection and informed drug use. Any occurrences of acute myopia and secondary angle closure glaucoma or other serious and/or unexpected adverse drug events in patients receiving TOPAMAX should be reported to Janssen-Ortho Inc. and the Bureau of Licensed Product Assessment at the following addresses:

Janssen-Ortho Inc.
19 Green Belt Drive
Toronto, ON
M3C 1L9
Tel: 1-800-567-3331, from 9 a.m. to 5 p.m. Monday to Friday, Eastern Standard Time
Fax: 416-382-5982 or 1-866-767-5865.

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Bureau of Licensed Product Assessment
Therapeutic Products Programme
HEALTH CANADA
Address Locator: 0201C2
Ottawa, ON
Tel: 613-957-0337
Fax: 613-957-0335
Email: cadrmp@hc-sc.gc.ca

The ADR Reporting Form can be found in The Compendium of Pharmaceuticals and Specialties on the TPD web site along with the ADR Guidelines at:

http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/forms/adverse_e.pdf

http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guides/adr/adr_guideline_e.pdf

Janssen-Ortho Inc. is committed to providing you with the most current product information available for the management of your patients receiving TOPAMAX. For literature references or any additional information concerning TOPAMAX please contact our Medical Information Department at 1-800-567-3331, from 9 a.m. to 5 p.m. Monday to Friday, Eastern Standard Time or access our web site at http://www.janssen-ortho.com

Sincerely,

Wendy Arnott, Pharm. D.
Vice-President,
Medical, Quality, Regulatory and Linguistics