Ortho-McNeil Pharmaceutical, Inc.
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IMPORTANT DRUG WARNING

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 postmarketing experience in more than 825,000 patients.

As of August 17, 2001 there have been 23 reported cases: 22 in adults and 1 in pediatric patients. It is generally recognized that postmarketing 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 judgment 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 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 judgment of the treating physician. Other measures, in conjunction with discontinuation of TOPAMAX, may be helpful.

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

Under PRECAUTIONS

Information for Patients

Patients taking TOPAMAX should be told to seek immediate medical attention if they experience blurred vision or periorbital pain.

You can further our understanding of adverse events by reporting all cases to Ortho-McNeil at the contact numbers below or to the FDA MedWatch Program by phone 1-800-FDA-1088, by fax 1-800-FDA-0178, by mail (using postage-paid form) MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or via www.fda.gov/medwatch.

A copy of the full Prescribing Information is enclosed for your reference. If you have any questions regarding TOPAMAX Tablets and TOPAMAX Sprinkle Capsules, please feel free to call Ortho-McNeil Medical Affairs Division at 1-800-682-6532.

Sincerely,

Joseph Hulihan, MD
Director, CNS Research