



Ortho-McNeil Pharmaceutical, Inc.
1000 Route 202, PO Box 300
Raritan, NJ 08869-0602
908 218-6000 Telephone

IMPORTANT DRUG WARNING

Dear Healthcare Professional:

The prescribing information for TOPAMAX[®] (topiramate/topiramate capsules) Tablets/Sprinkle Capsules has been revised to provide updated information about oligohidrosis (decreased sweating) and hyperthermia, which have been reported in topiramate-treated patients. Oligohidrosis and hyperthermia may have potentially serious sequelae, which may be preventable by prompt recognition of symptoms and appropriate treatment. This updated information is based on clinical trial and postmarketing experience in more than 2 million patients worldwide.

Reports have primarily involved children. Most cases have occurred in association with exposure to elevated environmental temperatures and/or vigorous activity, and children should be observed closely under these conditions. In the majority of patients, TOPAMAX therapy has been continued. Proper hydration before and during activities such as exercise or exposure to warm temperatures is recommended.

As of February 2002, the rate for spontaneous postmarketing reports of all potential cases of oligohidrosis is approximately 35 per 1,000,000 patients treated and 1.6 per 1,000,000 patients treated for serious or medically significant oligohidrosis or its sequelae. It is generally recognized that postmarketing data are subject to substantial under-reporting.

The following has been added to the TOPAMAX prescribing information:

Under WARNINGS

Oligohidrosis and Hyperthermia: Oligohidrosis (decreased sweating), infrequently resulting in hospitalization, has been reported in association with TOPAMAX use. Decreased sweating and an elevation in body temperature above normal characterized these cases. Some of the cases were reported after exposure to elevated environmental temperatures.

The majority of the reports have been in children. Patients, especially pediatric patients, treated with TOPAMAX should be monitored closely for evidence of decreased sweating and increased body temperature, especially in hot weather. Caution should be used when TOPAMAX is prescribed with other drugs that predispose patients to heat-related disorders; these drugs include, but are not limited to, other carbonic anhydrase inhibitors and drugs with anticholinergic activity.

Under PRECAUTIONS

INFORMATION FOR PATIENTS

Patients, especially pediatric patients, treated with TOPAMAX should be monitored closely for evidence of decreased sweating and increased body temperature, especially in hot weather.

You can further our understanding of adverse events by reporting all cases to Ortho-McNeil at the contact numbers listed 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 to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787) or via www.accessdata.fda.gov/scripts/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,

A handwritten signature in black ink, appearing to be 'JH', written in a cursive style.

Joseph Hulihan, MD
Director, CNS Research