Topamax (topiramate): Recall - Musty Odor

U.S. Food & Drug Administration

AUDIENCE: Risk Manager, Pharmacy, Patients

ISSUE: Ortho-McNeil Neurologics Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., is recalling two lots of Topamax (topiramate) 100mg Tablets. The recall stems from four consumer reports of an uncharacteristic odor thought to be caused by trace amounts of TBA (2,4,6 tribromoanisole). While not considered to be toxic, TBA can generate an offensive odor and a small number of patients have reported temporary gastrointestinal symptoms. There have been no reported serious adverse events caused by the presence of TBA in Topamax.

BACKGROUND: Topamax is indicated as initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures; as adjunctive therapy for adults and pediatric patients ages 2 − 16 years with partial onset seizures, or primary generalized tonic-clonic seizures, and in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome; and for adults for the prophylaxis of migraine headache.

RECOMMENDATION: Patients taking Topamax 100mg Tablets who experience an uncharacteristic odor associated with their medication should return the tablets to their pharmacist, and contact their healthcare professional if they have questions.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[04/14/2011 - Press Release [3] - Ortho-McNeil]

SOURCE [4]

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http://www.mdtmag.com/news/2011/04/topamax-topiramate-recall-musty-odor?qt-recent_content=0

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
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