

MEDICATION ALERT: Ortho-McNeil Recalls Two Lots of TOPAMAX to Address "Musty Odor"

(April 14, 2011) - On Friday, April 14th, Ortho-McNeil Neurologics Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., announced its voluntary recall of two lots of TOPAMAX® (topiramate) 100mg Tablets. These two lots were shipped between 10/19/2010 and 12/28/2010 and distributed in the U.S. and Puerto Rico. While the recall encompasses approximately 57,000 bottles of TOPAMAX®, the company believes there are fewer than 6,000 bottles remaining in the marketplace. The recall stems from four consumer reports of an uncharacteristic odor thought to be caused by trace amounts of TBA (2,4,6 tribromoanisole).

Package Description	NDC Code	Lot Number	Expiry
TOPAMAX® (topiramate) TABLETS 100mg Bottles of 60 Tablets	50458-641-65	0KG110	06-2012
		0LG222	09-2012

TBA is a byproduct of a chemical preservative sometimes applied to wood often used in the construction of pallets on which products are transported and stored. In January 2010, we instituted a number of actions to reduce the potential of TBA contamination, including requiring suppliers to verify that they do not use pallets made from chemically-treated wood. An internal investigation is underway with our suppliers to evaluate the potential source of this TBA issue. In addition, we are working with peer companies to better understand how and where TBA is entering and impacting our supply chains and what we can do to further mitigate this exposure.

The voluntary recall, being implemented in cooperation with the U.S. Food and Drug Administration (FDA), was initiated after enhanced surveillance and complaint monitoring programs escalated odor-related reports. While not considered to be toxic, TBA can generate an offensive odor and a very small number of patients have reported temporary gastrointestinal symptoms. As it relates to TOPAMAX®, there have been no reported serious adverse events caused by the presence of TBA.

Ortho-McNeil Neurologics has initiated this recall at the wholesale and retail (pharmacy) level and is communicating this information to these customers. The Company does not anticipate a product shortage resulting from this action.

The US Food and Drug Administration (FDA) has also posted information about the recall on its website, stating along with Ortho McNeil that 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. The company also encourage patients or healthcare professionals can also contact the TOPAMAX® Line at 1-866-536-4398 (Monday – Friday, 9 am – 5pm ET). Additional information from Ortho McNeil about the recall can be found on Topamax.com, RxForSafety.com, and OrthoMcNeilNeurologics.com.

The FDA recommends that healthcare professionals and patients 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.htm¹
- [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

TOPAMAX® 100mg Tablets are yellow debossed with “OMN” on one side and “100” on the other. This information is posted on the Epilepsy Foundation website, <http://epilepsyfoundation.org/epilepsyusa/news/Ortho-McNeil-Neurologics-Voluntarily-Recalls-Two-Lots-of-TOPAMAX.cfm> and at the US FDA website, <http://epilepsyfoundation.org/epilepsyusa/news/Ortho-McNeil-Neurologics-Voluntarily-Recalls-Two-Lots-of-TOPAMAX.cfm>

Source: Ortho-McNeil Neurologics and U. S. Food and Drug Administration.