



URGENT DRUG PRODUCT RECALL

4/14/2011

Dear Wholesaler/Distributor or Pharmacist,

Ortho-McNeil Neurologics, Division of Ortho-McNeil Janssen Pharmaceuticals, Inc. is initiating a voluntary recall of the TOPAMAX[®] 100mg tablet lots referenced below. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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

Dates of Distribution:

These two lots were shipped between 10/19/2010 and 12/28/2010.

Reason for Recall:

An investigation into consumer complaints for musty moldy odors revealed some bottles may contain trace amounts of 2,4,6 tribromoanisole (TBA).

Potential Health Hazard:

There is a low likelihood of patients experiencing serious adverse events resulting from exposure to TBA in these lots of TOPAMAX[®]. No serious adverse events in relation to TBA exposure have been reported in relation to the impacted lots. Of the complaints received for odor, some patients also reported gastrointestinal symptoms. To facilitate continuity of care it is important to note that patients should continue to take the product as prescribed if there is no unusual odor present.

IMMEDIATE ACTION TO BE TAKEN: (Note that this recall is being executed to the DISPENSING PHARMACY)

Wholesalers:

1. Please examine your inventory to determine if you have any of the referenced lots. If so, discontinue distribution and use of the product from those referenced lots and quarantine the product.
2. If you are a distributor and have further distributed any of these lots please forward this communication and the PI enclosed (not the BRC) to your customers.
3. Please instruct your customers to contact Stericycle at the number below to obtain a product return package.



4. Record the quantity of referenced product in inventory on the Business Reply Card and Packing Slip, which are included with this letter.
5. Mail the Business Reply Card to Stericycle even if you do not have the referenced product.
6. Return the referenced product and the Packing Slip using the prepaid UPS Return Service shipping label to:

Stericycle, Inc.
Event Number 2397
2670 Executive Dr., Suite A
Indianapolis, IN 46241

Pharmacies:

1. Please examine your inventory to determine if you have any of the referenced lots. If so, discontinue distribution and use of the product from those referenced lots and quarantine the product.
2. Contact Stericycle at the number below to obtain a product return package.

Stericycle 1-866-792-5453 (Monday – Friday, 8 am – 5 pm ET)

3. Please do not return product to your wholesaler – contact Stericycle for a product return package and follow instructions in the return package to receive appropriate credit.
4. If there is no unusual odor associated with the product patients should continue to take their TOPAMAX[®] as prescribed to facilitate continuity of care.
5. If you or your customers have any medical inquiries regarding TOPAMAX[®] or any other product-related questions, please contact the TOPAMAX[®] Line at 1-866-536-4398 **(Monday – Friday, 9 am – 5pm ET)**. Information can also be found at www.TOPAMAX.com.

Credit will be based on the customer's TOPAMAX[®] acquisition price in effect as of the date of this letter and issued in the form of a check or credit memo through customers' authorized wholesaler or specialty distributor. This is applicable for the recalled lots only. Recalled product must be returned by July 29, 2011 to be eligible for credit.

We appreciate your immediate attention and cooperation in this matter. **If you have any questions or need assistance with product return, contact Stericycle at 1-866-792-5453 (Monday – Friday, 8 am – 5 pm ET).**

We sincerely regret the inconvenience that this has caused both you and your patients.

Please see enclosed full prescribing information.