



March 4, 2011: Notice on FDA Announcement Regarding TOPAMAX® (topiramate)

The Food and Drug Administration (FDA) has announced increased precautions on the use of TOPAMAX in pregnancy. As the makers of TOPAMAX, Ortho-McNeil-Janssen Pharmaceuticals, Inc. is committed to patient safety and has worked closely with the FDA to update the TOPAMAX label, which is now posted on TOPAMAX product websites at <http://www.topamax.com/sites/default/files/topamax.pdf>.

The previous TOPAMAX label clearly outlined risks associated with use in pregnancy, and recommended cautious use in pregnant patients. The newly updated label strengthens this, and notes topiramate can cause fetal harm when administered to a pregnant woman. The new label also notes TOPAMAX has shown positive evidence of human fetal risk and should be used during pregnancy only when the potential benefits outweigh the risks of using the medication.

A “Dear Healthcare Professional” letter will be distributed explaining this important label update. Women taking TOPAMAX who are pregnant, nursing or could become pregnant should discuss their individual cases with their healthcare providers.

Healthcare professionals and consumers can call 1-800-JANSSEN (1-800-526-7736) for more information. For complete information on this FDA announcement, please refer to the Agency’s website at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm245594.htm> .

Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) provides medicines for an array of health concerns, including central nervous system disorders, such as schizophrenia and epilepsy; women's health; urology; gastrointestinal conditions; and infectious diseases. The company strives to provide innovative, high quality, safe and effective treatments and continually seeks new opportunities to offer solutions for unmet health care needs. Ortho-McNeil-Janssen Pharmaceuticals, Inc. is headquartered in Titusville, New Jersey.

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