

Janssen Inc.

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VIA FAX

December 17, 2012

Dear Healthcare Professional:

Subject: Updates to TOPAMAX[®] (topiramate) Product Monograph

Janssen Inc. would like to inform you that over the past year the TOPAMAX[®] Product Monograph has been extensively updated. These updates include the addition of new sections as well as updates to existing ones. A listing of the updated/new sections is provided below.

WARNINGS AND PRECAUTIONS

Special Populations, EPILEPSY, Pregnant Women (text added regarding fetal harm and metabolic acidosis)

Women of Childbearing Potential (New subsection, includes text on risk of fetal harm)

Labour and Delivery (includes text on the development of topiramate-induced metabolic acidosis)

Nursing Women (New subsection)

Pediatrics < 2 years of age (New subsection)

Fetal Toxicity (New subsection, includes text on causality and increased risk for congenital malformations)

Pregnancy Registry Data (added data from the NAAED Pregnancy Registry)

Hyperammonemia and Encephalopathy (added data on adolescents and pediatric patients < 2 years old)

Hyperammonemia/Encephalopathy with Concomitant Valproic Acid (VPA) (New subsection)

Hypothermia with Concomitant Valproic Acid (VPA) Use (New subsection)

Endocrine and Metabolism

Oligohydrosis and Hyperthermia (added anhidrosis)

Metabolic Acidosis (added data on pediatric patients < 2, 6-15 and patients > 16 years old)

Information for Patients (updated to reflect other changes to WARNINGS AND PRECAUTIONS)

DRUG INTERACTIONS

Valproic Acid: (added text on concomitant use associated with hypothermia)

Other Drug Interactions (added text on oral contraceptives)

Any cases of serious or unexpected adverse reactions in patients receiving TOPAMAX[®] should be reported to Janssen Inc. or Health Canada.

Drug Safety Department Janssen Inc. 19 Green Belt Drive Toronto, Ontario M3C 1L9 Or call toll free at 1-866-825-7122 Or email to dsscanscan@joica.jnj.com Or fax to 1-866-767-5865

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect

Call toll-free at 1-866-234-2345

Complete a Reporting Form and:

- Fax toll-free to 1-866-678-6789, or

- Mail to: Canada Vigilance Program

Health Canada

Postal Locator 0701E

Ottawa, Ontario

K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the [Adverse Reaction Reporting](#) section. The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties*.

The updated Product Monograph is available on the Janssen website, at www.janssen.ca/product/192. Should you have any questions or require additional information regarding the use of TOPAMAX® (topiramate), please contact Janssen Inc. Medical Information Department at 1-800-567-3331 or 1-800-387-8781 from 9:00 a.m. to 5:00 p.m., Monday through Friday, EST.

Sincerely,

Janssen Inc.

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