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TOPAMAX®(topiramate) Tablets and SPRINKLE capsules: ADDITIONAL WARNINGS AND PRECAUTIONS - VISUAL FIELD DEFECTS

Dear Healthcare Professional,

Janssen-Cilag Pty Ltd would like to inform you of important safety information for TOPAMAX® (topiramate).

Serious Risk with Use of TOPAMAX

New safety information has been added to the Warning and Precautions section of the TOPAMAX Data Sheet (DS):

Visual field defects have been reported in patients receiving topiramate independent of elevated intraocular pressure. In clinical trials, most of these events were reversible after topiramate discontinuation. If visual problems occur at any time during topiramate treatment, consideration should be given to discontinuing the drug.

Visual Field Defects are a recognised adverse reaction for topiramate as described in the Adverse Effects section of the DS. Based on cumulative data from a recent review of post-marketing safety databases, and clinical trials, this additional safety Information has been added in the **Warning and Precautions** section of the DS to increase awareness of this serious risk.

If visual problems occur at any time during topiramate treatment, consideration should be given to discontinuing TOPAMAX.

Patients taking TOPAMAX should be told to seek immediate medical attention if they experience blurred vision, visual disturbances or periorbital pain. Patients should be informed and counselled about the risk of Visual Field Defects, and advised to read the Consumer Medicine Information.

Please refer to the DS for complete information on TOPAMAX® tablets and TOPAMAX® SPRINKLE capsules. The DS is available on the Medsafe website <http://www.medsafe.govt.nz/> or from Janssen's Medical Information Department on 0800 800 806.

Adverse Event Reporting

Janssen is committed to ensuring that our products are used safely and effectively. Healthcare professionals should report any suspected adverse reactions associated with the use of TOPAMAX to Janssen Medical Information Department on 0800 800 806 or via email to: medinfo@janau.jnj.com and/or the Centre for Adverse Reactions Monitoring (CARM) in Dunedin on 03 479 7247 or by fax 03 479 7150 or email to carmnz@otago.ac.nz.

If you have further questions, please contact Janssen Medical Information on 0800 800 806 or medinfo@janau.jnj.com.

Yours sincerely,

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