janssen
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

17 March, 2015

TOPAMAX® (Topiramate): Serious Risk with Use of TOPAMAX® (topiramate), VISUAL FIELD DEFECTS have been reported in patients receiving topiramate independent of elevated intraocular pressure.

Dear Healthcare Professional,

Janssen Cilag Scientific office would like to inform you of important safety information for TOPAMAX® (Topiramate), an antiepileptic drug approved for Epilepsy and Migraine.

The safety and well-being of patients who use Janssen products are our highest priority.

Janssen Cilag scientific office would like to inform you of the following:

Summary:

- New safety information will be added to the Warnings and Precautions section of the TOPAMAX® (Topiramate) prescribing information.

  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.

- Patients should be informed and counseled about the risk of Visual Field Defects.

Additional Information:

- Visual Field Defects are a recognized adverse reaction for Topiramate (see prescribing information). Based on cumulative data from a recent review of post-marketing safety databases and clinical trials, additional safety information and guidance on this side effect will be added to the Warnings and Precautions section of the prescribing information in order to increase awareness of this serious risk.

- Patients taking TOPAMAX® should be informed to seek immediate medical attention if they experience blurred vision, visual disturbances, or periorbital pain.
- As stated in this warning, it is important to consider discontinuing Topiramate if visual problems occur at any time during treatment with this drug.

Janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson

The information in this letter has been approved by the Saudi Food and Drug Authority.

Call for reporting

Any suspected adverse events should be reported to the national spontaneous reporting system according to the national regulations.

SFDA (National pharmacovigilance and drug safety Center)
Email to: npc.drug@sfda.sa
Fax: +966-11-2057662
Online: http://ade.sfda.gov.sa/

Or

You can contact company scientific office at:
Email to: GCC-PV2@Its.jnj.com
Fax: +966-11-2153190

Janssen –Cilag scientific office manager:
Ph. Abdul Aziz Saleh Bin Amer

2015-4-5