FOR DISPENSARY USE ONLY

WARNING FOR WOMEN AND GIRLS

Topamax▼ (Topiramate)

Pregnancy Prevention Programme

Topiramate must be prescribed and dispensed according to the Topiramate Pregnancy Prevention Programme.

Topiramate is teratogenic. **Children exposed in utero have a higher risk for congenital malformations, low birth weight and being small for gestational age.** There may also be an increased risk for neurodevelopmental disorders. Please refer to the Healthcare Professional Guide for further information.

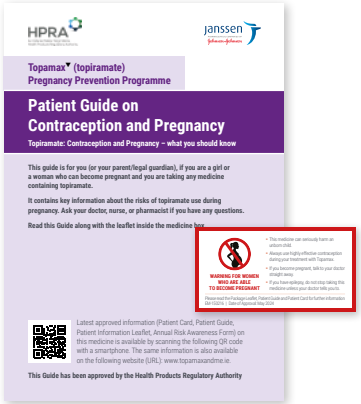
IMPORTANT ACTIONS FOR PHARMACISTS

Every time you dispense topiramate to girls or women of childbearing potential:

- Remind patients of the higher risk of congenital malformations, low birth weight and being small for gestational age and the possibility of an increased risk of neurodevelopmental disorders.
- Reinforce to the patient the need for highly effective contraception during treatment and for at least 4 weeks after stopping treatment.
- Remind patients of the need to plan for pregnancy and for at least annual specialist review.
- Patient Card: Provide a copy or ensure the patient received it in the box. Discuss its contents every time you dispense topiramate. Advise the patient to keep it with them.
- Patient Guide: Ensure the patient received it.
- Dispense topiramate in the original package with the outer warning. In the interim period until the carton is updated ensure that the warning sticker provided is attached to the outer carton.
- Dispensing topiramate outside of original packaging should be avoided. In situations where this cannot be avoided, always provide a copy of the package leaflet and a patient card, and add a sticker with the warning to the outer packaging.
- Please ensure to check the SmPC for complete information.

Please ensure you cascade this important information to all dispensary staff.

See the Healthcare Professional Guide and Summary of Product Characteristics for further information.


HPRA

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Topamax▼ (topiramate)
Pregnancy Prevention Programme

Patient Guide on
Contraception and Pregnancy

Topiramate: Contraception and Pregnancy – what you should know

This guide is for you (or your parent/legal guardian), if you are a girl or a woman who can become pregnant and you are taking any medicine containing topiramate.

It contains key information about the risks of topiramate use during pregnancy. Ask your doctor, nurse, or pharmacist if you have any questions.

Read this Guide along with the leaflet inside the medicine box.

WARNING FOR WOMEN WHO ARE ABLE TO BECOME PREGNANT

Latest approved information (Patient Card, Patient Guide, Patient Information Leaflet, Annual Risk Awareness Form) on this medicine is available by scanning the following QR code with a smartphone. The same information is also available on the following website (URL): www.topamaxandme.ie.

This Guide has been approved by the Health Products Regulatory Authority

Copies of the TOPAMAX (topiramate) Patient Guide, Patient Card, warning sticker and Poster can be reordered from Janssen by contacting our medical information team at **medinfo@its.jnj.com** or by calling **Medical Information** on **1800 709 122**.

The Patient Guide and Card can also be downloaded from the HPRA website www.hpra.ie. Enter «Topamax» or «topiramate» in the search box and then click on «EdM» next to any of the medicines that appear. They can also be downloaded from www.medicines.ie, where they will be found linked with entries for medicines containing topiramate.

CALL FOR REPORTING

▼ This medicinal product is subject to additional monitoring and it is therefore important to report any suspected adverse events related to this medicinal product. Healthcare professionals are asked to report suspected adverse events via: HPRA Pharmacovigilance, Website: www.hpra.ie. Adverse events should also be reported to Janssen Sciences Ireland UC on 0044(0)1494 567447 or email dsafety@its.jnj.com.