PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

TOPAMAX▼ (Topiramate): PREGNANCY PREVENTION PROGRAMME
Annual redistribution of Educational Materials

30 July 2025

Dear Pharmacist,

Further to the introduction of the **Pregnancy Prevention Programme** for topiramate-containing medicinal products in July 2024, please find enclosed the **educational materials** developed to prevent the risk of topiramate exposure during pregnancy. These materials are being sent to you as a part of the annual redistribution. Please note that there were no changes to the safety information in any of the materials. The scope of this letter is to remind you to always follow the instructions of the Pregnancy Prevention Programme.
These materials have been approved by the Health Products Regulatory Authority (HPRA).

Enclosed please find for use in your practice:

- **1 Healthcare Professional Guide** – includes guidance on the actions for healthcare professionals on implementing the Pregnancy Prevention Programme.
- **1 Patient Guide** - to be provided to all girls and women of childbearing potential when topiramate is prescribed.
- **1 Patient Card** - pharmacists should ensure a patient card is provided to all female patients of childbearing potential each time topiramate is dispensed. The patient card is now included in the Topamax carton.

Additionally, specific pharmacy materials are enclosed:

- 1 Pharmacy shelf barker
- 1 sheet of Warning stickers with pictogram
- 1 Pharmacy Poster

You are asked to display the shelf barker and poster in the dispensary as a visual reminder to pharmacy staff of the Pregnancy Prevention Programme, the warnings related to the use of topiramate and the need to counsel female patients on the risks. The warning stickers should be used when Topamax is dispensed outside of the original packaging. Please contact us if you need additional copies of these materials.

Electronic copies of the Patient Guide, Healthcare Professional Guide, Annual Risk Awareness Form and the Patient Card are available on www.medicines.ie and www.topamaxandme.ie . An electronic copy of these educational materials can also be found on the HPRA website at www.hpra.ie (enter 'Topamax' or 'topiramate' in the search box and click on 'EdM' next to any of the medicines that appear). Additional copies of all materials can be requested from Janssen by contacting our medical information team at medinfo@its.jnj.com or by calling Medical Information on 1800 709 122.

Pharmacists are reminded that:

- Topiramate can cause major congenital malformations and foetal growth restriction when used during pregnancy. Recent data also suggest a possibly increased risk of neurodevelopmental disorders (NDD) including autism spectrum disorders, intellectual disability and attention deficit hyperactivity disorder (ADHD) following topiramate use during pregnancy.
- Contraindications apply for the treatment of epilepsy:
    - in pregnancy, unless there is no suitable alternative treatment;
    - in women of childbearing potential not using highly effective contraception. The only exception is a woman for whom there is no suitable alternative but who plans a pregnancy and who is fully informed about the risks of taking topiramate during pregnancy.
- Topiramate for prophylaxis of migraine is already contraindicated in pregnancy and in women of childbearing potential not using highly effective contraception.
- Treatment of female children (in the case of epilepsy) and women of childbearing potential (for epilepsy and migraine) should be initiated and supervised by a physician experienced in the management of epilepsy or migraine. The need for treatment should be reassessed at least annually.
- Due to a potential interaction, women using systemic hormonal contraceptives should be advised to also use a barrier method.
- For women of childbearing potential currently using topiramate, the treatment should be reevaluated to ensure that the measures of the pregnancy prevention programme are followed.

PHARMACISTS are asked to take the following IMPORTANT ACTIONS when dispensing Topamax to female patients:

1. **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**
2. **Reinforce to the patient the need for highly effective contraception.**
3. **Remind patients of the need to plan for pregnancy and for annual specialist review.**
4. **Patient Card: Ensure that the patient received it in the box. Discuss its contents every time you dispense topiramate. Advise the patient to keep it with them.**
5. **Patient Guide: Ensure the patient received it.**
6. **Dispense topiramate in the original package with the outer warning.**
7. **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.**
8. **Please ensure you cascade this important information to all dispensary staff.**
9. **Display the shelf barker and poster in your dispensary as visible reminders to staff of the Pregnancy Prevention Programme, the warnings related to the use of topiramate and the need to counsel female patients on the risks.**
10. **Please ensure to check the SmPC for complete information.**

Call for reporting

Adverse events should be reported. ▼ 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 any suspected adverse events via: HPRA Pharmacovigilance, Website: www.hpra.ie. Adverse events should also be reported to Janssen Sciences Ireland UC a Johnson & Johnson Company on 0044 1494 567447 or at dsafety@its.jnj.com.

Company contact point

If you have further questions, please do not hesitate to contact the Janssen Medical Information department on telephone number: 1800 709 122 or email medinfo@its.jnj.com

Yours sincerely,

Brid Seoighe
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Dr Bríd Seoighe

Medical Director
Janssen Sciences Ireland UC