Janssen Sciences Ireland UC

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PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

3rd July 2024

TOPAMAX▼ (Topiramate): PREGNANCY PREVENTION PROGRAMME Introduction of New Educational Materials

Dear Pharmacist,

Further to the Dear Healthcare Professional Communication (DHPC) dated 1st November 2023 regarding the introduction of a new **Pregnancy Prevention Programme** for topiramate-containing medicinal products, **new educational materials** have been developed to prevent the risk of topiramate exposure during pregnancy and support the implementation of the Pregnancy Prevention Programme. These materials have been approved by the Health Products Regulatory Authority (HPRA).

Enclosed please find for use in your clinical 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 Annual Risk Awareness Form:** this should be discussed and completed by the doctor with all female patients of childbearing potential treated with topiramate – at treatment initiation (or when menarche is reached), at each annual visit, when a pregnancy is planned or if a pregnancy occurs.
- **25 Patient Cards:** pharmacists should ensure a card is provided to all female patients of childbearing potential each time topiramate is dispensed. The card will be included within the pack of Topamax products in the future.

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Additionally, specific pharmacy materials are enclosed:

- 1 Pharmacy shelf barker
- 25 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 are to be added to the outer carton in the interim period until the carton is updated to include the new warning. These warning stickers should also be added when Topamax is dispensed outside of the original packaging.

Electronic copies of the Patient Guide, Healthcare Professional Guide, Annual Risk Awareness Form and the Patient Card are available on www.medicines.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.
- New 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.

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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: 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.**
5. **Patient Guide: Ensure the patient received it.**
6. **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.**
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.**

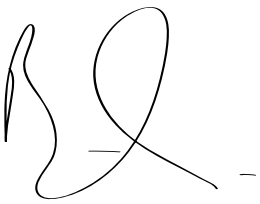
Call for reporting

▼ 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.

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 faithfully,



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