Janssen Sciences Ireland UC

Address: Airton Road, Tallaght, Dublin, D24 WR89
Tel +353 (0) 1 466 5200
Fax +353 1 431 1058
www.janssen.ie

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 Healthcare Professional,

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.
- **5 Patient Guides:** this should be used when discussing the risks of exposure to topiramate during pregnancy and be provided to all girls and women of childbearing potential being prescribed topiramate.
- **10 Annual Risk Awareness Forms:** 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.
- **5 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.

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.

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Healthcare professionals 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.

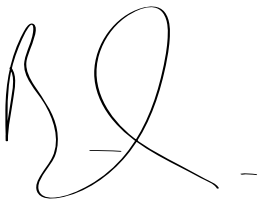
Call for reporting

▼ 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,



Dr Bríd Seoighe
Medical Director, Janssen Sciences Ireland UC

Registered office: Barnahely, Ringaskiddy, Co. Cork, Ireland