

Topamax (topiramate)

23/11/2023

Dear Healthcare Professional,

On 11 October 2023, the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh) endorsed new measures recommended by EMA's Pharmacovigilance Risk Assessment Committee (PRAC) in September 2023 within the framework of an Article 31 Referral Procedure to avoid exposure of children to topiramate-containing medicines in the womb, because the medicine may increase the risk of neurodevelopmental problems after exposure during pregnancy.

Topiramate-containing medicines are used in the European Union (EU) for the treatment of epilepsy and prevention of migraine.

Topiramate is already known to cause serious birth defects when used during pregnancy and the product information for topiramate monocomponent products already contain information about the increased risk of congenital malformations and a number of measures to reduce exposure of pregnant women are described. At present, topiramate must not be used to prevent migraine during pregnancy and patients who can become pregnant must use effective birth control when using topiramate. For patients using topiramate for the treatment of epilepsy, the medicine should not be used during pregnancy unless there is no other suitable treatment available.

The Committee considered it necessary to implement additional risk minimisation measures and tools as educational materials for healthcare professionals in the form of a healthcare professional guide, including a risk awareness form to be completed with the patient, and for patients in the form of a patient guide. These measures are put in place to increase awareness of healthcare professionals and patients on the risks of adverse outcomes after in utero exposure to topiramate, and to highlight the measures of the pregnancy prevention programme aiming at minimising pregnancy exposure during treatment with topiramate-containing products.

The Committee also recommended a patient card to be placed inside or affixed to one side of the outer packaging as well as a warning on the outer packaging to warn WCP on the risks to be pregnant while using topiramate.

Following the adoption of the PRAC recommendations by the CMDh, these measures will be implemented in all Member States. The product information for topiramate-containing medicines will be updated to further highlight the risks and the measures to be taken while patients and healthcare professionals will be provided with educational materials regarding the risks of using topiramate during pregnancy, and a patient card will be provided to the patient with each medicine package.

Based on the above plan, the Educational Materials developed for Topamax (topiramate), as approved by the Maltese Medicines Authority, are provided within this educational pack.

These include:

- **The Healthcare professional guide including a risk awareness form, which contains**
 - information on the risks of topiramate if taken during pregnancy
 - information on the conditions of topiramate prescription in female patients
 - Risk Awareness Form for female children and women who are able to become pregnant while treated with topiramate
- **The Patient Guide, which contains information on**
 - what are the risks of taking topiramate during pregnancy
 - what patients need to remember when taking topiramate
- **The Patient Card for women and girls who are able to become pregnant, which will be part of the product packaging and contains information**
 - on product's potential to seriously harm an unborn child if taken during pregnancy
 - on the need for contraception and Pregnancy Prevention
- **The Summary of Product Characteristics**

For additional information regarding the provided educational materials for Topamax please kindly contact Janssen's Local Representative, AM Mangion, by using one of the following methods:

Phone: 00356 2397 6888

Email: medicalaffairs@ammangion.com

Website: www.ammangion.com.mt

We thank you in advance for your attention and we remain at your disposal for any further information.

Yours sincerely,
Emmanouil Koutalas



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