جمجوم فارما
Jamjoom Pharma

Dear Healthcare Professional Communication

Date:5th December 2022

Topiramate (Alevio™): Increased risk of neurodevelopmental disorders in infants whose mothers used Topiramate during pregnancy

Dear Healthcare Professional,

This letter is sent from Jamjoom Pharma, in agreement with Saudi Drug and Food Authority (SFDA), would like to inform about risk of neurodevelopmental disabilities in children whose mothers took Topiramate during pregnancy.

Summary

- A large observational study that found a link between prenatal exposure to Topiramate and an increased risk of autism spectrum disorders, intellectual disability, and neurodevelopmental disorders.
- Pregnancy testing should be done prior to starting Topiramate in a woman of childbearing potential, and the patient should be fully informed of the hazards of using the Topiramate during Pregnancy.

Background on the safety concern:

Topiramate is used:

- Prevent migraine headaches in adults after consideration of possible alternative treatment options
- Alone to treat seizures in adults and children aged older than 6 years
- With other medicines to treat seizures in adults and children aged 2 years and older.

The Nordic register-based study of antiepileptic drugs in pregnancy (SCAN-AED) is a population-based cohort including 4.5 million mother child pairs, the most important findings were robust and dose dependent associations between prenatal Topiramate exposure and neurodevelopmental disorders. These associations persisted after accounting for potential confounding factors.

The results further demonstrated that prenatal exposure to several common antiseizure medication (ASM) dual therapies was associated with an increased risk

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العنوان البريدي: ٦٢٦٧، جدة - ٢١٤٤٢، المملكة العربية السعودية، الإدارة : ت: ٠٠٩٩ ٦١٤ ١٢ ٩٦٦ +، ف: ٠٠٨٨ ٦١٤ ١٢ ٩٦٦ +

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of neurodevelopmental disorders within the same range as prenatal Topiramate exposure, even without these ASMs being one of the drugs used. The population- based cohort found a clear risk of adverse neurodevelopment in children exposed to Topiramate, particularly at doses of 100 mg or more per day. Prenatal Topiramate exposure is associated with an increased risk of being born small for gestational age, and with an increased risk of congenital malformations. High risks for congenital malformations have been associated with daily doses of more than 100 mg. Few studies have assessed cognitive and behavioural child outcomes after prenatal Topiramate exposure.

When appropriate, counsel pregnant women and women of childbearing potential about alternative therapeutic options is advisable. Women of childbearing potential who are not planning a pregnancy to use effective contraception while using Topiramate, keeping in mind that there is a potential for decreased contraceptive efficacy when using estrogen-containing birth control with Topiramate.

References:

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10. https://www.ema.europa.eu/en/news/prac-starts-review-topiramate-use- pregnancy-women-childbearing-potential

Please refer to the Summary of Product Characteristics (SPC) of Alevio (Topiramate) for more detailed information.

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The information in this letter has been approved by the Saudi Food and Drug Authority (SFDA).

Call for Reporting

Healthcare professional should report suspected adverse reactions associated with this product in accordance with the national spontaneous reporting system:

SFDA (National Pharmacovigilance Center):
Email: npc.drug@sfda.gov.sa
Telephone: 19999
Online: http://ade.sfda.gov.sa

Company Contact Points:
If you have further question or require additional information, please contact our local safety department at:

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Corporate Office: Tel: +966 12614 0099 Ext #3259/ #3055
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Yours sincerely,
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Jr. Manager-Pharmacovigilance & QPPV

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المعلومات الدوائية و اليقظة الدوائي
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