Medicines & Healthcare products
Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted]
By email: [redacted]

2 May 2024

Dear [redacted],

FOI 24/335 topiramate health advice

Thank you for your request of 7 April under the Freedom of Information Act for information about the side effects of topiramate.
You have asked:

> Have there been any related studies that may suggest this drug can have side affects:
> - that almost put a patient into depression in a way as to they loose interest in general life?
> - There appetite is up and down?
> - There memory has lowered?
> - They know longer interact in a conversation it's like they are now in a depression state as to slowing them down there existence
> - is now terrible sleepy all the time ,
> - reported blurred vision ,
> - generally in a low state
>
> Can this type of drug cause these symptoms as we know everyone is different but if issues can start via a pregnancy then there most be reports on this drug?

Like all medicines, topiramate may cause side effects in some people. Clinical trials were conducted to evaluate the safety and effectiveness of topiramate in the treatment of epilepsy and prevention of migraine and these studies formed the basis of the authorisation for topiramate held by Janssen-Cilag Ltd and approved in 1995.

The Summary of Product Characteristics (SmPC) for healthcare professionals and the Patient Information Leaflet (PIL) which is supplied in each package of medicine outline the known side effects of topiramate. These documents are produced for all medicines and are available on the website of the Medicines and Healthcare Products Regulatory Agency (MHRA)[1] and other online sources such as the Electronic Medicines Compendium[2]. The SmPCs and PILs are updated as needed to reflect what is known about each medicine.

You ask about a number of side effects. These are all included as possible side effects in the SmPC and PIL for topiramate and I have provided information on each of these below.

Side effect	**Frequency of side effect currently listed in SmPC and PIL**
Depression	Very common (it may affect more than one in 10 people)
Increased appetite	Uncommon (it may affect up to one in 100 people)
Decreased appetite	Common (it may affect up to 1 in 10 people)
Memory lowered (loss of memory, problems with memory and problems with concentration)	Common (it may affect up to 1 in 10 people)
Sleepy (sleepiness, tiredness)	Very common (it may affect more than one in 10 people)
Blurred vision	Common (it may affect up to 1 in 10 people)
Low state (depressed mood)	Common (it may affect up to 1 in 10 people)

Further information on the possible side effects of topiramate can be found in the PIL which accompanies the medicines and is available here[3].

MHRA continually monitors the safety of medicines, including topiramate. One of the sources of data we use to monitor the safety of medicines is reports of suspected side effects from patients and healthcare professionals that are submitted through the Yellow Card Scheme. The reports received for topiramate can be accessed on the MHRA website[4].

If you are taking topiramate and are concerned about side effects that you are experiencing, you should discuss them with your doctor. You can also report any suspected side effects through the Yellow Card Scheme. Further information on the scheme and how to report can be found on the MHRA website[5].

If you have a query about the information provided, please reply to this email.

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[1] MHRA Products | Home
[2] Home - electronic medicines compendium (emc)
[3] Hreferralspcen (medicines.org.uk)
[4] info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_001007394921.zip&agency=MHRA
[5] Information | Making medicines and medical devices safer (mhra.gov.uk)

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

Safety and Surveillance
MHRA