



MHRA

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United Kingdom

www.gov.uk/mhra

23rd October 2023

Dear

FOI 23/710

Thank you for your FOI request dated 26th September 2023, where you requested the following information:

“How many yellow card reports have there been between 2019 - 2022 on the teratogenic effects of the anti-convulsant drugs below when taken during pregnancy:

- I. Sodium Valproate*
- II. Topiramate*
- III. Lamotrigine*
- IV. Levetiracetam*
- V. Carbamazepine”*

I can confirm that the MHRA does hold this information; however, it is exempt from release under Section 21 of the FOI Act – information accessible by other means: the information you have requested is already in the public domain.

Interactive Drug Analysis Profiles (iDAPs) contain complete listings for all medicines of all UK spontaneous suspected adverse drug reactions received by the MHRA and are available to view on our website: <https://yellowcard.mhra.gov.uk/iDAP/>. On this platform, you will be able to search for the anti-convulsant drugs you listed and find the reported suspected adverse reactions associated with them. You can also refine your search to have reports from the System Organ Class (SOC) to Congenital, familial and genetic disorders by selecting only this SOC, as well as have reports from 2019 until 2022 by updating the ‘Year received’. It is important to note that there is an iDAP for each licensed medicine by drug substance, not by drug brand. (Please note, that for sodium valproate, you will need to select the substance valproic acid).

When considering the attached spontaneous data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a



medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

The MHRA continuously monitors the safety of medicines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: <https://www.medicines.org.uk/emc/> for details on the possible side effects.

I hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance

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