Medicines & Healthcare products
Regulatory Agency

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United Kingdom
**gov.uk/mhra**

[redacted]

21st May 2024

Dear [redacted]

**FOI2024/00068**

Thank you for your Freedom of Information (FOI) request dated 25th April 2024 where you requested: *"Are you able to release any yellow card data on Isotretinoin please?"*

Further to your request, I can confirm that we do hold this information however it is exempt from release under Section 21 of the FOIA (Information accessible by other means), as this is already publicly available and can be found on our website via our interactive Drug Analysis Profiles (iDAPs).

iDAPs allow users to view all adverse reactions reported for a particular drug substance, such as isotretinoin, and also filter the reports so the charts and tables display subsets of the data, such as limiting the year reports are received by the Agency. It is particularly important to note that reports are not confirmed side effects to a medication and that incidence cannot be derived since a number of factors influence reporting of ADRs.

When using the Interactive Drug Analysis Profile, you should remember that:

- The likelihood of experiencing an adverse drug reaction when taking a medicine cannot be estimated from the data in the Interactive Drug Analysis Profile. This is because we have limited information about how many people have taken the medicine without experiencing a reaction.
- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine may have caused the adverse drug reaction. The existence of an adverse drug reaction report in the Interactive Drug Analysis Profile does not necessarily mean that the medicine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse drug reaction. Sometimes reactions can be part of the condition being treated rather than being caused by a medicine.
- Many factors have to be considered when assessing whether a medicine has caused a reported adverse drug reaction. When monitoring the safety of medicines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different medicines by comparing the numbers presented in the Interactive Drug Analysis Profiles. Reporting rates can be influenced by

many factors including the seriousness of the adverse drug reactions, their ease of recognition and the extent of use of a particular product. Reporting can also be stimulated by promotion and publicity about a product.

Please be aware that this data should not be used as a list of side effects to isotretinoin, nor should this data to be used to estimate the frequency of side effects or to compare the safety profile of different medicines. All established undesirable effects for the available isotretinoin products can be found in the Summary of Product Characteristics (SmPC) for healthcare professionals and the Patient Information leaflet (PIL), both of which can be found on the MHRA products website.

I hope the information provided is helpful, but if you are dissatisfied with the handling of the part of your request handled under FOI, 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
Medicines and Healthcare products Regulatory Agency