Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

14 February 2024

Dear [redacted]

FOI 24/106

Thank you for your FOI request dated 31 January 2024 requesting information on Yellow Card reports related to sodium oxybate.

You can view all suspected adverse reactions reported to the MHRA via the Yellow Card scheme on our website as interactive Drug Analysis Profiles (iDAPs). The iDAP for gamma-hydroxybutyric acid (sodium oxybate) can be viewed here.

iDAPs provided on our website are regularly updated, however please be aware that there is a time lag of around one month from receipt of a report to it appearing in the iDAP. It is also important to note that each individual iDAP on our website is accompanied by additional context for interpreting the Yellow Card data displayed in the iDAP. The outcome associated with each reported adverse reaction is not provided on the published iDAP. The iDAP can however be filtered to display information from reports with a fatal outcome only.

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 Group

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has

not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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