



Medicines & Healthcare products
Regulatory Agency

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Recipients name: [REDACTED]
[REDACTED]

30 January 2024

Dear [REDACTED]

FOI 24/006:

Thank you for your email, dated 2 January 2024, in which you requested the Clinical and Non-clinical overviews for Topiramate Rosemont 10mg/ml Oral Suspension (PL 00427/0245) and Topiramate Rosemont 20mg/ml Oral Suspension (PL 00427/0246).

In response to your request, please find attached the Clinical Overview (Module 2.5) and Non-clinical Overview (Module 2.4) submitted to support the initial application for Topiramate Rosemont 10mg/ml Oral Suspension (PL 00427/0245) and Topiramate Rosemont 20mg/ml Oral Suspension (PL 00427/0246). The documentation has been redacted under Section 40 (Personal information) of the Freedom of Information (FOI) Act.

Disclosure of information subject to Section 40 (Personal information) would be an infringement of personal data. Section 40 (Personal information) is an absolute exemption, and no consideration of the public interest is required.

We now consider this FOI request closed. If you have a query about this letter, please contact the MHRA FOI Licensing mailbox using the email address listed below.

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 2 months of the date you receive this response and addressed to: info@mhra.gov.uk, quoting reference FOI 24/006.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, and Cheshire, SK9 5AF.

Yours sincerely,

The FOI Licensing Team

Email: FOILicensing@mhra.gov.uk

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