



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

[MHRA Website](#)

Our Ref: **FOI2025/00100**

3 April 2025

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 5 February. You wrote:

'Please could you provide a copy of the Clinical Overview for Omeprazole 1 mg/ml, powder for oral suspension (PL 34111/0005)?'

MHRA Response

The Agency has completed its search for the information you have requested and we are able to confirm that we do hold the information.

The clinical overview is provided with this response. Please note that some of the information has been redacted. This information cannot be disclosed and is being exempt from release for the reasons below.

- **Section 43(1) and Section 43(2) Commercial interests**

Release of the information would be likely to cause harm to the third party's commercial interests. We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information. As a qualified exemption, this exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released.

In applying Section 43(1) and Section 43(2), the agency has conducted a test of public interest to ensure that the public interest in withholding the information is balanced against the public interest in disclosing the information.

In this case, we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity). On balance, we find that withholding the information from release outweighs our obligation to release.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>