

RE: FOI 23/942 - Freedom Of Information Request

[REDACTED]
Fri 05/01/2024 14:12

To: FOILicensing [REDACTED]
Cc: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

From: [REDACTED] On Behalf Of FOILicensing

Sent: Friday, January 5, 2024 11:21 AM

To: [REDACTED]

Cc: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>; FOILicensing <FOILicensing@mhra.gov.uk>

Subject: RE: FOI 23/942 - Freedom Of Information Request

Dear [REDACTED]

Thank you for your request for information, dated Monday, December 4, 2023, where you asked:

“Please can you let me know whether Mexetil Capsules (Mexiletine Hydrochloride) MA Holder Boehringer Ingelheim Limited have been registered in the UK. If yes, please can you provide the following:

Corresponding PL number
Corresponding SPC and PIL
Registration Date
Discontinuation Date and reason for discontinuation”

Our response:

Mexitil Capsules have been previously approved but have since been cancelled. The PL numbers are as follows:

PL 00015/0062R	Mexitil Capsules 50mg
PL 00015/0063R	Mexitil Capsules 100mg
PL 00015/0064R	Mexitl Capsules 200mg

MA holder: Boehringer Ingelheim Limited

Date of grant: 2 August 1990

Cancellation date: 1 August 1998 (PL 00015/0063R) and 1 July 2008 (PL 00015/0062R, PL 00015/0064R). After a reasonable search of our records, I have not been able to identify a specific reason for the cancellations.

I have attached the most recent SPCs and PILs for Mexitil Capsules. We do not hold the PIL for Mexitl Capsules 100 mg. Please note limited redactions have been made to the leaflet document to remove extraneous information that was not part of the Patient Information Leaflet.

We trust that you will find this information of use. However, If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted online via an electronic form: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

Or in writing to:

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

Yours sincerely,

HQA FOI team

From: [REDACTED]
Sent: Monday, December 4, 2023 9:36 AM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 23/942 - Freedom Of Information Request

You don't often get email from [REDACTED]

Dear Sir/Madame,

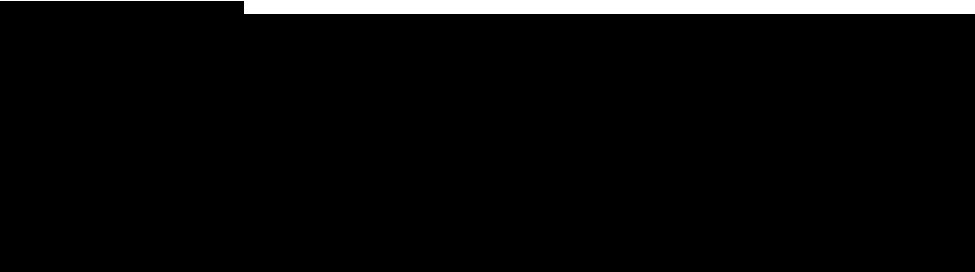
My name is [REDACTED]



Please can you let me know whether Mexetil Capsules (Mexiletine Hydrochloride) MA Holder Boehringer Ingelheim Limited have been registered in the UK. If yes, please can you provide the following:

- a. Corresponding PL number
- b. Corresponding SPC and PIL
- c. Registration Date
- d. Discontinuation Date and reason for discontinuation

Really appreciate your help and Merry Christmas 😊

[REDACTED]





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