



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00307**

28 April 2025

Dear [REDACTED],

Thank you for your Freedom of Information (FoI) request received on 27th March 2025. You wrote:

*Yes please could I have the risk management plan for this and the list of adverse effects.
If a cost is incurred, I will be happy to pay (depending on how much)*

MHRA Response

We confirm that we hold the information you have requested.

Please see attached a copy of the requested Risk Management Plan (RMP). Information that has been redacted is exempt under Section 40 (Personal Information) of the FOI Act and is therefore withheld. Section 40 provides that personal information may be exempt from release where to do so would contravene data protection principles.

Further to your request, I can confirm up to and including 21st April 2025 the Yellow Card scheme has received a total of 115 UK spontaneous suspected Adverse Drug Reaction reports associated specifically with the product Fultium D3.

Please find the attached Product Analysis Print (PAP) for Fultium D3. This PAP contains complete data for all adverse reactions, or side effects reported up until 21st April 2025. Please refer to the attached information sheet for guidelines on how to interpret this.

As the data does not necessarily refer to proven side effects, you should refer to the Product Information Leaflet (PIL) and the Summary of Product Characteristics (SPC) which can be found here: [Search Results - \(emc\)](#)

When considering the spontaneous ADR data detailed above, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine or medicinal product, only that the reporter had a suspicion it may have. The fact that symptoms or events occur after use of a product, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the product. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines or vaccines during the first one to two years on the market and then falls over time.

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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