

FOI 23/944

Thank you for your email, dated 04/12/2023, in which you requested:

Palonosetron hydrochloride

“a copy of the Risk Management Plan and Public Assessment Reports for PL 41013/0022.”

We can confirm that the MHRA holds a copy of the requested RMP.

Information that has been redacted is exempt under Section 40 (Personal Information) of the Freedom of Information (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.

The PAR is publicly available and can be accessed at the following link: <https://products.mhra.gov.uk/product/?product=PALONOSETRON>

We 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.

Please remember to quote the reference number above in any future communications.

Yours sincerely,

FOI Team

Safety & Surveillance Group

Medicines and Healthcare Products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

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FOI Team,
Vigilance and Risk Management of Medicines Division