



Medicines & Healthcare products
Regulatory Agency

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[REDACTED]

29 August 2023

FOI 23/562

Dear [REDACTED]

Thank you for your information request, dated 31 July 2023, where you asked for any studies that were done for the two active components dicyclomine and doxylamine (without pyridoxine).

I am pleased to provide you with some of the information requested. The only study of dicyclomine and doxylamine (without pyridoxine) for which we hold information is the '8-way study' of Debendox/Bendectin referred to in previous correspondence, along with an unpublished report of follow-ups of pregnancy outcomes in this study and an earlier '4-way' study (about which we hold no information). The report of pregnancy outcomes is provided for your information; unfortunately the paper copy held by MHRA has text missing from the bottom of some pages.

Dicyclomine and doxylamine (in combination without pyridoxine) was one of the 8 interventions in the '8-way study'. The study findings (along with supplementary information) have been published by Zhang and Persaud (2017) and has therefore not been provided as part of this response as it is accessible by other means. The supplementary information in the Zhang and Persaud publication refers to '3-way' and '4-way' studies of Bendectin, in which dicyclomine and doxylamine (in combination without pyridoxine) appear to have been studied, but we hold no information about these studies.

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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 you receive this response and addressed to: info@mhra.gov.uk

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

If you were to remain dissatisfied 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 at:

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

Yours sincerely,

Safety and Surveillance

References

Zhang R, Persaud N. 8-Way Randomized Controlled Trial of Doxylamine, Pyridoxine and Dicyclomine for Nausea and Vomiting during Pregnancy: Restoration of Unpublished Information. PLoS ONE 2017 12(1): e0167609.
<https://doi.org/10.1371/journal.pone.0167609>