

FOI 24/236

FOILicensing <FOILicensing@mhra.gov.uk>

Tue 02/04/2024 12:08

To

Dear

Regarding your request for information on metformin and gliclazide, please see our responses below.

1. I would like to know the maximum recommended daily doses of the diabetic drugs Metformin and Gliclazide?  
**The maximum daily dose for metformin is 2000 mg taken as two or three divided doses for typical children and 3000 mg taken as three divided doses for typical adults. This information is available in the public domain, in the patient information leaflet for metformin products, a link to these is provided below:**  
<https://products.mhra.gov.uk/search/?search=metformin&page=1&doc=Pil&rerouteType=0>  
**The maximum daily dose for gliclazide in adults is 320 mg taken as two divided doses. This information is available in the public domain, in the patient information leaflet for gliclazide products, a link to these is provided below:**  
<https://products.mhra.gov.uk/search/?search=gliclazide&page=1&doc=Pil>
2. What the reasoning is behind the maximum recommendations in daily intake?  
**The reasoning behind maximum recommendations in daily intake are based on the efficacy and tolerability of a medicine. In other words, the maximum daily dose is the dose at which the benefit/risk for a medicine is still positive.**
3. In what circumstances would it be permitted to exceed the recommended maximum daily intake doses?  
**Metformin and gliclazide should not be used outside the terms of their licence and this includes not exceeding the recommended maximum daily intake dose. If there are particular circumstances where exceeding the recommended dose may be recommended to meet the specific needs of a patient, this would be the responsibility of the prescribing doctor.**
4. What would be the repercussions of a patient being prescribed 1000mg of Metformin and 240mg of Gliclazide daily?  
**For an adult being prescribed 1000mg of metformin and 240mg of gliclazide daily, this is within the maximum daily dose for adults (see response to Question 1) and within the terms of their licences. Any decision on the dose of metformin and gliclazide for an individual patient would be made by the prescribing doctor.**

If you have a query about the information provided, please reply to this email.

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](mailto: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,  
FOI Team