Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00855**

01 September 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 1 August. You wrote:

> *Please could you provide a breakdown as below:*
>
> * *By age*
> * *By sex*
> * *What dose/preparation was the patient taking (Aclasta(tm) or Zometa(tm))*
> * *How long the medication was taken for, and whether it was stopped*
> * *Whether the patient had any pre disposing cardiac conditions*
> * *What the cardiac side effects were, and whether they were reversible (spontaneously, or on stopping the drug)*
> * *Was zoledronic acid considered to be cause of the fatal outcome*
>
> *In addition, with regard to the table of reactions by organ class in the Yellow Card reporting summary, please could you provide the same data but solely for Aclasta(tm) since, not only do those patients treated with Zometa(tm) have cancer, but they are given a more intense dosage regimen. This would then allow me to determine whether I would want to seek further detail for any more of the reactions, as per what I have requested for the cardiac side effects above.*

MHRA Response

The Agency has completed its search for the information you have requested, and we are able to confirm that we do hold the information you have requested.

Firstly, information regarding reports of zoledronic acid broken down by age and sex is exempt from release under **Section 21 of the FOIA** (information accessible by other means), as this is already publicly available. The MHRA publishes this information in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed here on the Yellow Card website. You will be able to access a

complete listing of all suspected adverse drug reactions (ADRs) that have been reported to the MHRA via the Yellow Card scheme for all of the Zoledronic Acid. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies.

When reviewing the data within an iDAP it is important to do so in the context of the essential guidance at the bottom of the report to ensure that you do not misinterpret the data. The data shown in these interactive profiles can be very useful in helping to identify possible medicine safety issues. However, this information does not present a complete overview of the potential side effects associated with specific medicines. Conclusions on the safety and risks of medicines cannot be made on the data shown in the Interactive Drug Analysis Profile alone.

Further to the other parts of your request, please see Annex 1, attached, which provides the following information:

* *What dose/preparation was the patient taking (Aclasta(tm) or Zometa(tm))*
* *How long the medication was taken for, and whether it was stopped*
* *What the cardiac side effects were, and whether they were reversible (spontaneously, or on stopping the drug)*
* *Was zoledronic acid considered to be cause of the fatal outcome*

Please note that responses to these questions on a Yellow Card form are not mandatory when reporting to the scheme, as such this information may not always be provided by the reporter

Regarding point one above we have understood your request to be regarding the dose and brand taken. Please note, Zoledronic acid is only licensed to be provided as an infusion in the UK. We have provided the start and stop date for the medication in order to determine the duration of the treatment. Please note whilst Annex 1 also provides the cardiac ADRs and the outcome reported, the ADRs can also be viewed via iDAPs and filtered as desired, including by year, age and sex.

Additionally, from the 95 spontaneous suspected ADR reports of Zoledronic acid and Cardiac disorders SOC, only 1 report included information regarding predisposing cardiac conditions. Please note patient medical history is not a mandatory field when reporting to the Yellow Card scheme.

While the MHRA carefully assesses Yellow Card reports to facilitate assessment of the link between a medicine and the reported adverse event, we do not verify reports or assign causality (i.e., whether the patient's reaction was caused by the medicinal product) at the level of individual reports. As such we do not hold information on whether zoledronic acid was the cause of a fatal outcome in these reports.

Lastly, and further to the second part of your request, please see Annex 2 which provides a Product Analysis Print for Aclasta which include all ADRs reported up to and including 01/09/2026.

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

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

- The number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine or vaccine and may be stimulated by promotion and publicity about a medicine or vaccine. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

- The MHRA continuously monitors the safety of medicines through a variety of pharmacovigilance processes, including the Yellow Card scheme. As part of our signal detection processes, all adverse reaction reports received by the Yellow Card scheme are assessed, and cumulative information is reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

We hope the information provided is helpful. 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.

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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