



Medicines & Healthcare products
Regulatory Agency

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[REDACTED]
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6th March 2024

Dear [REDACTED]

FOI 24/147 – The Yellow Card Scheme and definition of hypersensitivity.

Thank you for your email. Please find the responses to your questions below:

- Are we privy to what changes you have made if any to BIMZELX?

All changes or updates to medical advice or recognised side effects with regards to a medicine are included in the product information. This constitutes the labelling on the package, the Patient information Leaflet (PIL) and the Summary of Product Characteristics (SmPC, which is for healthcare professionals). These are available within the package when you receive the product, and online (these documents can be found on our website, [here¹](#) or on the electronic medicines compendium (emc), [here²](#)). Changes that concern serious or severe effects, those with a large public health impact, or those that require a change in clinical practice are additionally communicated via a Drug Safety Update, which is circulated to relevant healthcare professionals and patient groups and/or to healthcare professionals via a Direct Healthcare Professional Communication (DHPC). These communications can also be found on our website, [here³](#).

- What does the term hypersensitivity mean and how is it measured? This is the question I have been asking yet I do not have an answer.
 - I ask because UCB have not recommended the prescription of BIMZELX to people with hypersensitivity. So - how do medical practitioners assess hypersensitivity?

¹ <https://products.mhra.gov.uk/>

² <https://www.medicines.org.uk/emc>

³ <https://www.gov.uk/drug-safety-update>

The term hypersensitivity is a type of immune system disorder defined as an overreaction of your immune system to something that would not usually cause an immune response. This leads to allergy symptoms. Hypersensitivity is an umbrella term which can be used to describe reactions which can sometimes have some similar physical effects (for example itching, hives, anaphylaxis, sneezing, airway obstruction, swelling), but which have differing biological mechanisms. It is usually classified into four types; namely, type I (Immediate), type II (antibody-mediated), type III (immune complex-mediated), and type IV (cell-mediated or delayed-type). Further detail on these can be found [here](#)⁴.

In the context of a hypersensitivity reaction believed to be caused by a medicine or one of its ingredients, this is usually an immune-mediated reaction to the drug substance or one of the medicine's ingredients, symptoms of which can range from non-serious reactions such as rashes and itching to serious reactions such as anaphylaxis. It is often suspected if a patient experiences an allergic-type reaction after beginning a new medicine but it can be difficult to identify the cause of such reactions as they can have a delayed onset rather than immediate. With regards to how it is measured, sometimes healthcare professionals can perform skin testing or provocation testing if drug related hypersensitivity is suspected, however it is usually suspected based on symptoms and time-based relation to taking the medicine.

In the product information of a medicine and in the context of the study of a medicine, it is standard practice to advise that people with hypersensitivity to the medicine or its ingredients should not take the medicine. This is to make clear that people who are aware of a hypersensitivity from prior use of the medicine, or from use of another medicine or product that contains one of the ingredients, should not take the medicine. It is not routine clinical practice to test for hypersensitivity reactions prior to starting a patient on a medicine. Hypersensitivity is usually detected upon exposure. In clinical trials, patients are monitored for hypersensitivity reactions and the product information for Bimzelx advises that hypersensitivity reactions can occur and that patients should talk to their doctor or get medical help immediately if they notice signs of a serious allergic reaction such as:

- difficulty breathing or swallowing
- low blood pressure, which can make you dizzy or light-headed
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bump

I hope this information is helpful to you. If you have any further questions, please do not hesitate to contact us.

Yours sincerely,

FOI Team
Safety and Surveillance

⁴ <https://www.sciencedirect.com/topics/medicine-and-dentistry/hypersensitivity>