

Isotretinoin and suspected link with serious side effects: public and patients' views sought

To support a review of evidence on the possible association between the acne medicine, isotretinoin, and psychiatric and sexual disorders, a call for information has been launched today by the Medicines and Healthcare products Regulatory Agency (MHRA).

Patients and their families, healthcare professionals, researchers and organisations are being invited to contribute to the review through the [MHRA's call for information](#).

Isotretinoin is an effective medicine for severe forms of acne that has not responded to other treatments, however as with all medicines, there are suspected side effects, some of which can be severe.

An Expert Working Group is reviewing the available evidence relating to isotretinoin, and will advise whether the MHRA should take additional regulatory action, for example, improving the information for patients to help minimise the risks of psychiatric and sexual side effects, suspected to be associated with isotretinoin.

Dr. Sarah Branch, Director of Vigilance and Risk Management of Medicines at the MHRA, said:

We want patients taking isotretinoin to be informed of the risks and benefits and have recently issued a reminder to healthcare professionals.

All medicines can cause side effects, and we need to ensure that the benefits of taking isotretinoin outweigh the potential risks associated with this medicine. That is why we need people's help to gather information on psychiatric or sexual disorders, that they have suffered, and suspect to be associated with isotretinoin treatment.

We are asking patients, family members and healthcare professionals to contribute to the review so that the Expert Working Group has up-to-date information to consider. All information we receive will be treated confidentially.

We know this is a personal issue for anyone who suspects they have suffered psychiatric or sexual disorders with isotretinoin treatment, therefore we would appreciate any help you may be able to give us.

The MHRA will work with patients and their families, as well as healthcare professionals and organisations, to ensure everyone has an opportunity to contribute to the review. The agency is particularly interested to hear the experience of patients and families in the UK, but would also welcome contributions from those living outside the UK.

Details about the call for information, including what and how to submit, are [available here](#).

Any queries regarding the review or the call for information should email info@mhra.gov.uk or phone 020 3080 6000.

Due to its suspected side effects, isotretinoin should only be prescribed under the supervision of consultant dermatologists, to treat severe forms of acne that have not responded to antibiotics and topical treatments (creams or gels). Isotretinoin capsules are also known by the brand names Roaccutane, Reticutan, and Rizuderm in the UK.

Anyone in the UK who suspects they may have experienced a side effect with isotretinoin, or any other medicine, can submit a report to the Yellow Card Scheme. This helps makes medicines safer for everyone.