Medicines & Healthcare products Regulatory Agency

DRUG SAFETY UPDATE (DSU)

Isotretinoin – changes to prescribing guidance and additional risk minimisation measures

Specialisms: *Dermatology, Dispensing GP practices, General practice, Pharmacy, Psychiatry*

Summary

The Commission on Human Medicines (CHM) has endorsed changes to the risk minimisation measures for isotretinoin, following a review of the impact of the measures implemented in 2023. We ask healthcare professionals to review these new measures and supporting materials and integrate them into their clinical practice.

Second prescriber no longer required plus updated risk minimisation measures

Following the review of the impact of the 2023 risk minimisation measures for isotretinoin and the October 2025 survey of dermatology services, the CHM has recommended an updated approach to the prescribing requirements for isotretinoin. From today, healthcare professionals can prescribe isotretinoin to those under 18-years old without seeking the agreement of a second prescriber.

However alternative risk minimisation measures have been introduced to ensure isotretinoin continues to be prescribed and dispensed safely and all other existing risk minimisation measures continue to remain in place. The updated approach is designed to strengthen the Medicines and Healthcare products Regulatory Agency's (MHRA) ability to monitor safe prescribing while supporting patient access to treatment.

The associated Public Assessment Report contains further details of the data considered and advice given by CHM.

Advice for Healthcare Professionals:

Healthcare professionals are asked to review these new measures and supporting materials and integrate them into their clinical practice

Second prescriber requirement for under 18s no longer required

- the second prescriber regulatory requirement for patients under 18 years of age has been replaced by alternative risk minimisation measures. The product information for isotretinoin will be updated over the coming months to reflect this change. Services can implement this change immediately, although we acknowledge that some transition time may be required

New Risk Minimisation Measures

- the Acknowledgement of Risk Form for all patients has been updated. The digital version is now available online and should be used in clinical practice as soon as is feasible. Hardcopies will be available in the coming months (see section below for further information). The revised Acknowledgement of Risk Form:
  a) asks the patient to confirm that they understand the therapeutic indication of isotretinoin. The prescriber is also asked to confirm that isotretinoin is clinically indicated for the patient and that there is no other appropriate effective treatment. This provides additional safeguards on appropriate prescribing for all patients
  b) asks the patient to confirm that they understand they can seek a second opinion about their treatment
  c) has been streamlined to fit two pages
- a clinical audit of risk minimisation measures is to be developed and implemented by the British Association of Dermatologists (BAD). Healthcare professionals are expected to fully engage in the clinical audit which will be initiated in 2026 (see section below for further information)
- a patient information video has been produced by the BAD with oversight from the MHRA and CHM, to explain the risks associated with isotretinoin treatment in an accessible format. Healthcare professionals should advise patients to watch the video prior to starting treatment (see section below for further information). Patients will need to confirm they are aware of the video on the Acknowledgement of Risk Form

Existing Measures

- healthcare professionals should continue to follow the other existing measures including:
  - patients should continue to be counselled about the potential mental health and sexual side effects of isotretinoin, and monitoring of these side effects should continue to take place throughout treatment
  - patients of child-bearing potential should continue to be entered into the Pregnancy Prevention Programme (this also applies to other oral retinoid medications)
  - healthcare professionals should continue to use the patient reminder card and pharmacist checklist
  - prescribers should assess a patients' mental health before prescribing isotretinoin including the use of patient-reported outcome measures and ask patients about any sexual function concerns before prescribing isotretinoin

- prescribers should monitor patients for side effects including mental health and sexual function side effects at each follow up appointment including objective mental health patient reported outcome measures
- the Lead Prescriber, who initiates isotretinoin treatment, must have expertise in the use of systemic retinoids for the treatment of severe acne and a full understanding of the risks of isotretinoin therapy and monitoring requirements

Reminder of October 2025 changes to isotretinoin guidance

- healthcare professionals are also reminded about the updates and clarifications to the isotretinoin prescribing advice announced in October 2025:
  - follow-up consultations do not necessarily need to be in person (face to face) and could be remote if appropriate, however the first appointment should be in person
  - medically supervised pregnancy testing may be performed remotely with appropriate oversight to ensure tests are performed correctly and safely
  - patients should be asked about sexual function at follow up appointments, although by the third appointment, this may be brief

- healthcare professionals should continue to report any suspected adverse drug reactions associated with isotretinoin on a Yellow Card

Advice for Healthcare Professionals to Provide to Patients:

- isotretinoin is an effective treatment for acne. It should be used for acne that is severe or at risk of causing permanent scarring when other appropriate treatments have not been effective
- all medicines have side effects. Not every patient experiences side effects. Side effects of isotretinoin include possible mental health and sexual function side effects
- following a review of the impact of the current safety measures, a new monitoring approach has been put into place to ensure that isotretinoin continues to be given to patients safely and that patients are fully informed of the risk of side effects
- patients under 18 will no longer require the agreement of two independent healthcare professionals before they can begin treatment, however services who prescribe isotretinoin will take part in regular audits to ensure safe prescribing practices
- as with any medical treatment, all patients have the option to continue to seek a second opinion from another healthcare professional if they are unsure about starting treatment, your doctor will offer this to you during your first consultation
- a patient information video has been developed which explains when isotretinoin treatment should or should not be used for a patient, and potential side effects of isotretinoin. All patients are advised to watch this video before starting treatment

- although some measures related to isotretinoin are changing, the majority are remaining in place:
  - patients must continue to sign an Acknowledgement of Risk form to confirm that they understand the risk of side effects - your doctor will check that you understand the information in the form - make sure to keep your copy of the completed form safe. This form has been updated to confirm that the patient understands that isotretinoin is indicated for use with severe acne after other treatment options have failed
  - patients receiving isotretinoin treatment will continue to receive a Patient Reminder Card with important safety information – make sure you read the card and keep it safe
  - patients who are taking isotretinoin who may be able to get pregnant will continue to be entered into a Pregnancy Prevention Programme by their doctor, because isotretinoin can seriously harm an unborn baby if taken during pregnancy. Your doctor will explain what this involves
  - mental health will continue to be assessed before prescribing isotretinoin and patients will be asked about any sexual function concerns before prescribing isotretinoin
  - patients will continue to be monitored for side effects including mental health and sexual function side effects at each follow up appointment
- patients already being treated with isotretinoin should continue to follow their agreed treatment plan from their prescriber, but seek advice from their healthcare professional if they have any side effects or concerns
- report side effects associated with isotretinoin directly to the MHRA via the Yellow Card scheme

Background

Following the implementation of the recommendations of the Commission on Human Medicines (CHM) Isotretinoin Expert Working Group (IEWG) and Isotretinoin Implementation Advisory Expert Working Group (IIAEWG) in 2023, the MHRA has conducted a review of the impact of these measures and has sought advice from the CHM. To support the CHM in their decision making, in October 2025, the MHRA asked all dermatology services who prescribe isotretinoin to complete a survey regarding their service. The MHRA review and survey data was presented to the CHM to inform their recommendations on the regulatory requirements of isotretinoin.

The CHM reviewed and considered the effectiveness of the implementation of the new regulatory requirements for isotretinoin after considering all the available data.

The associated Public Assessment Report contains further details of the data considered and advice given by CHM.

Second Prescriber

The CHM conducted a review concerning the regulatory requirement for two independent prescribers when initiating isotretinoin therapy in patients under 18. The intention behind this requirement was to ensure that two clinicians agreed there were no alternative effective treatments before starting isotretinoin, thus providing greater oversight for young patients.

The CHM considered the risks of maintaining the requirement for two prescribers (specifically in relation to delays to treatment and reduced access) against the benefits gained from a second prescriber, in the light of new data from BAD and clinical practice. The CHM considered that there had been positive structural changes made to clinical pathways, to improve patient counselling and monitoring. The CHM also noted the limited treatment options for severe acne, which meant that there was little disagreement between prescribers regarding isotretinoin treatment.

Concerns were also noted about private practice adherence to regulations and limitations in available data from this sector. The October 2025 survey was conducted to improve the oversight of prescribing practices including in the private sector.

On the basis of the findings and results of the October 2025 survey, the CHM recommended replacing the two-prescriber requirement with other risk minimisation measures. These include an enhanced Acknowledgment of Risk Form, new clinical audit processes, and accessible patient information resources developed by the BAD.

These new measures will provide patients with the same level of information, continued monitoring and the option of a second opinion, whilst enabling the MHRA to strengthen monitoring of adherence to the risk minimisation measures.

The associated Public Assessment Report contains further details of the data considered and advice given by CHM.

Guidance on New Risk Minimisation Measures

New Acknowledgement of Risk Form for Patients

The Acknowledgement of Risk Form for all patients has been updated. The digital version is now available online and should be used in clinical practice as soon as is feasible. Hardcopies will be available to order in the coming months from the Marketing Authorisation Holders.

New Clinical Audit

A regular clinical audit of risk minimisation measures is to be developed and implemented by the BAD. Healthcare professionals are expected to fully engage in the clinical audit

which will be initiated in 2026. Relevant dermatology services were asked if they would commit to taking part in future clinical audits as part of our survey released in October 2025 and the vast majority (97%) of services who responded agreed to this. Based on this information, the CHM were able to advise removal of the two-prescriber requirement. The BAD will be in contact later in 2026 to explain what the audit will involve and what data will be required from services as part of the audit. Audits will continue on a regular basis in the future.

With each audit, the information will be gathered by the BAD and then submitted to the CHM for review. If there is evidence that services are not following the risk minimisation measures in place for isotretinoin, further regulatory measures will need to be considered.

Patient Information Video

A patient information video has been produced by the BAD, with oversight from the MHRA and CHM, to explain the risks associated with isotretinoin treatment in an accessible format. Healthcare professionals should advise patients to watch the video prior to starting treatment. For example, they may wish to send a link to the video to patients before their initial appointment takes place.

Patients will need to confirm they are aware of the video on the Acknowledgement of Risk form.

Reporting advice

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the Yellow Card website.
- the Yellow Card app; download from the Apple App Store or Google Play Store
- some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates.

Additional information

You can sign up to receive email notifications for Drug Safety Updates.

You can sign up to receive our monthly roundup of safety communications.

For any enquiries, please contact info@mhra.gov.uk

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