Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

January 2026

Summary of the latest safety advice for medicines and medical device users

Contents

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Isotretinoin – changes to prescribing guidance and additional risk minimisation measures

Access the full article

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.

Key Advice for Healthcare Professionals:

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

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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- The second prescriber regulatory requirement for patients under 18 years of age has been replaced by alternative risk minimisation measures.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 New Acknowledgment of Risk Form for Patients section for further information). The revised Acknowledgement of Risk Form:
  - 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
  - asks the patient to confirm that they understand they can seek a second opinion about their treatment
  - has been streamlined to fit into 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 New Clinical Audit 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 Patient Information Video section 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

Key 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

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- the agreement of two independent healthcare professionals will no longer be required for initiation of treatment in patients under 18, 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

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Improving Information Supplied with Gabapentinoids (Pregabalin/Gabapentin), Benzodiazepines and Z-Drugs

Access the full article

Specialisms: *General practice, Pain management and palliation, Psychiatry*

Summary

The MHRA has reviewed the warnings regarding addiction, dependence, withdrawal, and tolerance for gabapentin, pregabalin, benzodiazepines, and z-drugs. The findings (detailed in the Public Assessment Report) were that it was necessary to strengthen these warnings in the product information and on packaging to better inform healthcare professionals and patients of these known risks.

Key Advice for Healthcare Professionals:

- gabapentinoids (pregabalin and gabapentin), benzodiazepines and z-drugs are three classes of medicines used to treat a variety of conditions such as neuropathic pain, anxiety and insomnia. Specialist use of these medications for conditions such as epilepsy, or sedation during medical procedures are not included in this review
- all three classes of medications are known to pose risks of addiction, dependency, withdrawal and tolerance
- the Summary of Product Characteristics, Patient Information Leaflets and Outer Packaging of these medicines will have strengthened warnings to better communicate the risks of addiction, dependency, withdrawal and tolerance to healthcare professionals and patients. Updates are in progress and will be rolled out over the coming months
- prior to starting treatment with these medicines, a discussion should be held with patients to put in place a strategy for reducing or ending treatment. By doing this the risk of addiction, dependence, and drug withdrawal syndrome is reduced. NICE guideline, NG215, has resources that include visual summaries which are available to support these discussions. The Agency has also developed additional patient resources for benzodiazepines, gabapentinoids and z-drugs which highlight key messages concerning these risks and should be made available to patients when these medications are prescribed

- addiction and dependence are related but have distinct presentations. Healthcare professionals are reminded of the importance of using non-judgmental language when discussing these terms
- patients may find that treatment is less effective with chronic use and express a need to increase the dose to obtain the same level of symptom control as initially experienced. This could be a sign that the patient is developing tolerance. The risks of developing tolerance should be explained to the patient
- drug withdrawal syndrome may occur upon abrupt cessation of therapy or dose reduction. When a patient no longer requires therapy, it is advisable to taper the dose gradually to reduce symptoms of withdrawal. Tapering from a high dose may take weeks or months. Patients should be informed of this when the medication is first prescribed and should be encouraged to speak to their healthcare professional or prescriber before stopping their medicine. See NICE guideline NG 215 for identifying and managing withdrawal symptoms
- provide regular support especially to individuals at increased risk of drug withdrawal syndrome, such as those with current or past history of substance use disorder (including alcohol misuse) or mental health disorder
- addiction, dependence, withdrawal or tolerance in response to these medications can be reported via the Yellow Card scheme

Key Advice for Healthcare Professionals to Provide to Patients:

- as these medicines carry risks of addiction, dependence and withdrawal reactions, before starting treatment with these medicines, your healthcare professional should explain how long you might need to take them for, and how to stop safely. This helps reduce the risk of addiction, dependence, and drug withdrawal syndrome
- anyone can become physically dependent on these medicines, meaning that their body gets used to it, and this can cause them to have withdrawal symptoms if the medicine is suddenly stopped, or the dose is reduced
- drug addiction can feel like a strong desire to take the medicine, and difficulties in controlling medicine use (for example feeling like you want to take more or use the medicine when you shouldn't)
- addiction and dependence are related but they are not the same, being physically dependent on a medicine does not necessarily mean you are addicted to it
- drug tolerance can mean no longer feeling like the medicine is working well, or feeling that a higher dose is required to achieve the same symptom relief as before

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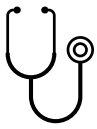
- if you want to stop taking your medicine there are additional resources to help you. Never stop taking your medication without asking a healthcare professional first
- if you are taking this medicine for epilepsy, you should keep taking it for as long as your doctor says it's needed
- if you find that your treatment is not working as well, you should speak to your healthcare professional about possible alternative treatment options, and you should never take more of your medicine than you have been prescribed
- when it is time to stop your medication, your healthcare professional will tell you how to gradually reduce the amount of medicine you are taking over time (known as dose tapering). This is very important to reduce the risk of drug withdrawal syndrome. Dose tapering can sometimes take weeks or months. Mild symptoms may still occur, but you should contact your healthcare professional if the withdrawal symptoms become intolerable



M6-C Artificial Cervical Disc, Spinal Kinetics LLC: New monitoring requirements for the risk of osteolysis (DSI/2026/001)

Access the full article

Specialisms: *General practice, Orthopaedics*

Device Details:

M6-C artificial Cervical Disc

Summary

The MHRA has conducted an assessment following reports of osteolysis and early device failure in the literature. The MHRA found that there was a delay in the manufacturer's communication of the risks of osteolysis, change in indications for use and updates to the product information to users and patients in the UK. Patients implanted with the M6-C artificial cervical disc should be informed of the risks of osteolysis, receive annual routine monitoring and discuss the need for further investigation and continued follow-up.

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Key Advice for Healthcare Professionals:

Clinical follow-up recommendation:

- trusts/ hospitals should review local records to identify patients implanted with the M6-C device and invite them for active monitoring of their implant
- all identified patients should be contacted to inform them of the active monitoring programme and advised to contact their surgeon if they experience any new or unexpected symptoms
- patients that have the M6-C device implanted should be actively monitored for signs and symptoms of osteolysis
- all patients should receive an anterior-posterior and lateral X-ray of the cervical spine on an annual basis that is reviewed clinically irrespective of whether they have symptoms
- follow the guidance from the British Association of Spine Surgeons
- if a patient has symptoms and/or osteolysis is suspected from their X-ray, further scanning such as CT or MRI will be required to evaluate the implant further. Appropriate follow-up should be adjusted based on an individual patient basis
- if a patient has osteolysis, surgeons should discuss the available options with them based on the clinical presentation of the patient. If revisional surgery is required, this should be carried out by a spinal surgeon with experience in revisional cervical spine surgery
- if hospitals need to prioritise patients for recall, patients with multi-level implantations of the M6-C device should be prioritised as the indications for use have been updated to exclude multi-level implantations

Key Advice for Healthcare Professionals to Provide to Patients:

- if you experience any new or unexpected symptoms including increasing neck pain, arm pain radiating from the neck, pins and needles in the hands or arm, weakness in the hands or arms, electric type sensations into the arms or body when moving the neck or weakness or loss of balance in the legs, speak to your implanting surgeon or the hospital where your surgery was performed in the first instance
- if you have had an M6-C device implanted, it is important you have had an X-ray in the last 12 months

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- if you have had an M6-C device implanted, you should expect to be contacted by your surgeon or implanting hospital. There is no need to contact your surgeon or implanting hospital directly if you have no new or unexpected symptoms

Letters, medicines recalls and device notifications sent to healthcare professionals in January 2026

Direct Healthcare Professional Communications

We received notification that the following Direct Healthcare Professional Communications were sent or provided to relevant healthcare professionals in January 2026:

- Xenpozyme▼ 20mg powder for concentrate for solution for infusion (olipudase alfa): Interim Supply of European Union Packs to Ensure Supply Continuity
- Tyenne 20 mg/mL concentrate for solution for infusion – PLGB 08828/0359 - Temporary Supply of Finnish/Swedish dual labelled stock
- Tyenne 20 mg/mL concentrate for solution for infusion – PLGB 08828/0359: Temporary Supply of Poland/Ireland dual labelled stock. *Sent to relevant stakeholders in December 2025.*
- Tyenne 20 mg/mL concentrate for solution for infusion – PLGB 08828/0359 - Temporary Supply of Finnish/Swedish dual labelled stock. *Sent to relevant stakeholders in December 2025.*

Medicine Recalls and Notifications

In January 2026, recalls and notifications for medicines were issued on:

Class 2 Medicines Recall: Mercury Pharmaceuticals Ltd, Paliperidone Mercury Pharma prolonged-release suspension for injection in pre-filled syringes, EL(26)A/01. Issued 20 January 2026.

Mercury Pharmaceuticals Ltd is recalling remaining stock of paliperidone pre-filled syringes as a precautionary measure due to Good Manufacturing Practice (GMP) deficiencies cited during a recent inspection at the finished product manufacturing site.

Class 3 Medicines Recall: Glenmark Pharmaceuticals Europe Limited, Fingolimod Glenmark 0.5 mg Hard Capsules, EL(26)A/02. Issued 21 January 2026.

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Glenmark Pharmaceuticals Europe Limited is recalling one batch after stability testing showed out-of-specification results. The batch is being recalled as a precautionary measure following test results that showed a delay in capsule dissolution.

Class 4 Medicines Defect Notification: Blumont Pharma Limited, Ocumont Eye Ointment 1% w/w, EL(26)A/03. Issued 27 January 2026.

Blumont Pharma Limited is reporting to the MHRA regarding the absence of Braille on the outer carton of one batch of Ocumont Eye Ointment 1% w/w (POM). It was identified that the Braille information was inadvertently omitted during the approval and release process.

Medical Device Field Safety Notices

Find recently published Field Safety Notices

Report suspected drug reactions and device incidents on a Yellow Card

Please continue to report suspected adverse drug reactions and device incidents. Your report will help us safeguard public health.

When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates and particularly if a side effect continued or started after treatment was stopped.

Report a medicine

Healthcare professionals should report via a Yellow Card to:

- 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)

Reporting for medical devices

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Yellow Card website in accordance with your organisations medical device policies and procedures

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Reporting for Patients

Report a medicine or medical device

Patients should report via a Yellow Card to:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store

News Roundup

Statins: update to product information on the role of the nocebo effect in muscle-related events

Following publication of a meta-analysis by the Cholesterol Treatment Trialists' (CTT) Collaboration on the effect of statin therapy on muscle symptoms, the MHRA reviewed evidence on the nocebo effect in relation to statins. The review concluded that updates to product information are appropriate to reflect current scientific understanding of the role of the nocebo effect in muscle-related events.
After internal assessment and advice from independent expert advisory group committees, changes to product information have been recommended to raise awareness of the meta-analysis findings. These include highlighting that:

- Statin therapy caused a small relative increase (3%) in the first reports of mild muscle pain or weakness largely confined to the first year of treatment.
- The likelihood of a first episode of muscle pain or weakness was higher with intensive statin regimens compared to moderate or less intensive regimens.
- More than 90% of muscle symptom reports among participants receiving statin therapy were not caused by the statin.

We are now implementing these updates across the statin drug class. For further details, please refer to the Summary of Product Characteristics and Patient Information Leaflets available on the MHRA website.

Increased semaglutide dose for adults with obesity – prescribing advice

Healthcare professionals prescribing semaglutide (Wegovy) for adult patients with obesity (BMI over 30) should note that the MHRA has now authorised a maximum weekly dose of 7.2 mg.

If needed, it can be used for weight management in adult patients with obesity only (those with a Body Mass Index (BMI) of 30kg/m² or higher), in addition to a reduced-calorie diet and exercise. Treatment should commence at 0.25 mg weekly, with increments every four weeks until the standard 2.4 mg dose is reached. The patient must stay on this dose for a minimum of 4 weeks. Only then, and if clinically indicated, may the dose be increased to 7.2 mg.

For the Wegovy 7.2 mg weight management dose, patients will need to inject three doses of 2.4 mg, one after each other on the same day. The injection sites should be spaced at least 5cm apart. Patients should be provided with advice on how to use injections safely at home. There may be some increased side effects, including gastrointestinal side effects, with higher dosing. For further information, please refer to the Summary of Product Characteristics (SmPC) for the medicine and see our full news story.

Any suspected side effects should be promptly reported through the MHRA Yellow Card scheme.

Epimax Ointment and Epimax Paraffin-Free Ointment: reports of ocular surface toxicity and ocular chemical injury

The Medicines and Healthcare products Regulatory Agency (MHRA) is reminding healthcare professionals of the Drug Safety Update regarding Epimax Ointment and Epimax Paraffin-Free Ointment. The MHRA continues to receive reports of ocular surface toxicity and ocular chemical injury where patients have been prescribed or advised to use these emollients on the face or around the eyes.

Healthcare professionals are reminded not to prescribe or advise the use of Epimax Ointment or Epimax Paraffin-Free Ointment on the face. They should also be aware that if these products come into contact with the eyes, patients may present with pain, swelling, redness or watering of eyes, sensitivity to light, blurred vision, burning or grittiness. Healthcare professionals should report suspected adverse reactions associated with Epimax Ointment or Epimax Paraffin-Free Ointment via local and national reporting systems. For full details please see the Drug Safety Update.

MMRV vaccine factsheet published

The MHRA has published a new MMRV vaccine factsheet, designed to provide information and guidance for parents and caregivers on the combined measles, mumps, rubella and varicella (chickenpox) vaccine.

The factsheet outlines the safety and effectiveness of the MMRV vaccine, who can receive it, and details on its introduction into the UK childhood immunisation schedule from 1 January 2026.

This resource is available for healthcare professionals to use when discussing MMRV vaccine safety and to support families and caregivers in understanding the protection it provides against potentially serious illness. For further details, view the full MMRV vaccine factsheet.

New MHRA guidance for healthcare professionals and the public on the use of mental health apps and technologies

The MHRA has published new online learning resources to help health and social care professionals and the public make informed choices about digital tools for mental health support.

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The resources were developed with NHS England's MindEd Technology Enhanced Learning programme:

- Resources for the general public
- Resources for health, social care, and education professionals – for nurses, GPs and mental health practitioners.

With digital tools such as symptom-tracking apps and virtual reality therapies now widely available, the MHRA has developed the new learning resources to explain:

- what technologies regulated as medical devices look like
- how to select or recommend a product appropriate for use
- how to report safety concerns using the MHRA Yellow Card scheme

MHRA Chair and Professor of Primary Care at the University of Oxford, Professor Anthony Harnden, said:

"As a GP, I've seen how patients can benefit from accessing digital tools alongside traditional forms of care. This guidance supports better conversations between clinicians and patients and helps everyone ask the right questions about whether a tool is right for them."

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