Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

December 2025

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

Contents

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News Roundup

Mesalazine and idiopathic intracranial hypertension

Access the full article

Specialisms: *Emergency medicine, General practice, GI, hepatology and pancreatic disorders, Neurology, Pharmacy*

Summary

Idiopathic intracranial hypertension (IIH) has been very rarely reported in patients treated with mesalazine. Following a recent review, warnings for idiopathic intracranial hypertension are being added to the product information for all mesalazine products.

If idiopathic intracranial hypertension occurs in patients, discontinuation of mesalazine should be considered.

Key Advice for Healthcare Professionals:

- idiopathic intracranial hypertension (IIH) has been very rarely reported in patients receiving mesalazine
- the number of reports in the UK is very low
- patients using any form of mesalazine should be warned to look for signs and symptoms of IIH including severe or recurrent headache, visual disturbances or tinnitus
- remain vigilant of signs and symptoms of IIH in patients taking mesalazine and act promptly with a multidisciplinary approach, involving clinicians managing the patient's mesalazine as well as neurology, neurosurgery and ophthalmology teams as appropriate

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- if symptoms of IIH occurs, discontinuation of mesalazine should be considered and management of the symptoms should begin immediately
- caution is advised when prescribing for patients who have previously diagnosed or suspected IIH

Key Advice for Healthcare Professionals to Provide to Patients:

- there have been very rare reports of increased pressure within your skull known as idiopathic intracranial hypertension (IIH) in some patients receiving mesalazine
- IIH is not normally life threatening; however, in rare cases can cause serious vision problems which must be monitored and treated where possible
- tell your doctor immediately if you experience progressively more severe and recurrent headache, disturbed vision, ringing or buzzing in the ears, back pain, dizziness, or neck pain, as these could be symptoms of IIH

Rybelsus ® (semaglutide tablets): transition to new formulation and risk of medication error

Access the full article

Specialisms: *Care home staff, Dispensing GP practices, Endocrinology, diabetology and metabolism, General practice, GI, hepatology and pancreatic disorders, Nutrition and dietetics and Pharmacy*

Summary

There is a risk of patient harm arising through medication error during a transition period where the original and new formulation of Rybelsus ® tablets, which have different stated mg doses but are bioequivalent, will both be available on the market. Medication error may result in overdose if healthcare professionals prescribe more than one tablet per day of the new formulation to try to match the dose to the old strengths. This could affect disease control and increase the risk of side effects. Healthcare systems are advised that a co-ordinated response is required to manage switching patients to the new formulation. Healthcare professionals should be aware that the original formulation is anticipated to be available until approximately 31st January 2026 however, original formulation stock of imported Rybelsus ® may be within supply chains beyond this date.

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Key Advice for Healthcare Professionals:

- the new formulation of Rybelsus ® has increased bioavailability therefore lower strength tablets achieve the same drug exposure and clinical effect as the previous formulation
- ensure all relevant staff members are familiar with the new dosing range:

Initial formulation (one oval tablet)	Bioequivalent	New formulation (one round tablet)
3 mg (starting dose)	=	1.5 mg (starting dose)
7 mg (maintenance dose)	=	4 mg (maintenance dose)
14 mg (maintenance dose)	=	9 mg (maintenance dose)

- details of the new formulation can be found in the Direct Healthcare Professional Communication distributed by the Marketing Authorisation Holder in September 2025
- the two formulations will temporarily co-exist on the market until approximately 31st January 2026 however, original formulation stock of imported Rybelsus ® may be within supply chains beyond this date
- Rybelsus ® should always be taken as **one** tablet per day. Taking more than this will result in overdosing, which affects disease control and increases the risk of adverse events
- prescribe patients starting Rybelsus ® treatment the new formulation once it is available in your prescribing system
- systematically switch patients who are currently on Rybelsus ® to the new formulation once it is available in your prescribing systems
- inform patients about the change in formulation and strength when the new formulation is prescribed or dispensed
- ensure that patients are aware that tablets with the new formulation and lower strengths will have the same effects as the tablets with the initial formulation and higher strengths
- document in the patient's notes that the change has been undertaken and communicate to other parts of the system where required
- refer patients to the patient transition guide for further information
- report medication errors or near misses via local risk management systems and medication errors resulting in patient harm on the Yellow Card website

Key Advice for Healthcare Professionals to Provide to Patients:

- Rybelsus ® tablets have been modified so that the medicine is more easily absorbed by your body. The new and modified tablets are just as effective as the old tablets,

but have a smaller dose. It will work the same as the old tablets even though the dose is different. The tablets will now be smaller and round in shape.

- continue to take **one** tablet per day
- refer to the patient transition guide for further information
- if you are unsure about what dose you are taking, speak to your pharmacist or prescriber
- report suspected adverse drug reactions via the Yellow Card website

Letters, medicines recalls and device notifications sent to healthcare professionals in December 2025

Direct Healthcare Professional Communications

We received notification that the following Direct Healthcare Professional Communications were sent or provided to relevant healthcare professionals in December 2025:

- Keppra OSL 150mL - dosing syringe change from 3 to 5mL
- Mivacurium 2mg/ml, Cisatracurium 2mg/mL solution for injection, administration instructions for specified batches where glass particles may be present
- Tegretol® 100 mg/5ml Liquid (carbamazepine): Limitation of use in neonates. *Sent to relevant stakeholder in November 2025.*

Any further DHPCs sent in December will be included in our January Roundup

Medicine Recalls and Notifications

In December 2025, recalls and notifications for medicines were issued on:

Class 2 Medicines Recall: Hameln Pharma Ltd, Clarithromycin 500 mg powder for concentrate for solution for infusion, EL(25)A/53. Issued 11 December 2025.

Hameln Pharma Ltd is recalling certain batches of Clarithromycin 500 mg powder for concentrate for solution for infusion.

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Class 3 Medicines Recall: Activase Pharmaceuticals Limited, Prednisolone 5mg Soluble Tablets, EL(25)A/54. Issued 15 December 2025.

Activase Pharmaceuticals Limited is recalling two batches of Prednisolone 5mg Soluble Tablets as a precautionary measure due to a limited number of reports of blister pockets becoming swollen over time.

Class 4 Medicines Defect Notification: Hameln Pharma Ltd, Flamingo Pharma UK Ltd, Amitriptyline Hydrochloride 10mg, 25mg, 50mg Tablets, EL(25)A/52. Issued 10 December 2025.

Flamingo Pharma UK Ltd has informed the MHRA that the Patient Information Leaflet (PIL) in the products listed in the notification do not contain all the required safety information.

Any further medicines recalls and notifications published in December will be included in our January Roundup

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

Reporting for medical devices

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app

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- some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)
- 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

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

Patient and family experiences inform antidepressant safety information review

An Expert Working Group (EWG) advising the Commission on Human Medicines (CHM), has concluded a detailed review into how the potential risks associated with 28 antidepressant medicines are communicated to patients within the Patient Information Leaflet (PIL).

The MHRA launched the review after concerns were raised by families and patients that current safety warnings in the PILs for these medicines did not clearly explain certain side effects – specifically suicidal behaviours, and sexual dysfunction that may continue after the treatment is stopped.

The CHM advised the MHRA on a series of updates for the communication of risks of suicidal behaviours. These are to be taken forward in the coming months and include:

- updates to the PILs, to provide clarity and strengthen the wording
- introduction of a patient card
- introduction of an ancillary leaflet for patients

The revised text will be further developed through user testing to ensure it is as clear and effective as possible, and the MHRA is exploring a range of engagement options to take this advice forward.

The MHRA is working with the National Institute for Health and Care Excellence (NICE), the British National Formulary (BNF), and the Royal Colleges of General Practice and Psychiatrists to improve consistency of safety messaging in a range of additional communications.

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The CHM advised updates to the PILs for some antidepressants on the risk of sexual dysfunction where symptoms continue after stopping treatment to better reflect the views of patients and evolving data.

We will communicate further when the regulatory process is finalised with the manufacturers of the 28 antidepressants included in the review and the new materials are available.

Vaccine factsheet published

The MHRA has published a new vaccine safety patient factsheet designed to help patients understand more about vaccines, including what they contain, how they are made, and how they work.

The factsheet outlines the rigorous testing vaccines undergo during development as well as the ongoing monitoring systems that ensure their safety once they are on the market.

This resource is now available for healthcare professionals to use when discussing vaccine safety with patients and to help patients and the public understand more about the steps taken to ensure that vaccines remain safe and effective. For further details, view the full vaccine safety patient factsheet.

Call for evidence: Regulation of AI in Healthcare

The MHRA has launched a Call for Evidence to support the work of the National Commission into the Regulation of AI in Healthcare. Contributions are invited from across all four nations of the UK and internationally to inform the Commission's recommendations. Anyone can take part, and we would especially like to hear from healthcare professionals. Input received will help shape a regulatory framework that protects patients, supports responsible innovation and encourages growth.

The National Commission brings together global AI leaders, clinicians, regulators and patient advocates to advise the MHRA on the future of AI regulation in healthcare. Submissions can be made up to 2 February 2026. For further details view the full article.

MHRA updates guidance on the Health Institution Exemption to support safe use of medical devices

Patients across England, Wales and Scotland could benefit from updated guidance on the Health Institution Exemption published by the Medicines and Healthcare products Regulatory Agency (MHRA).

This will support hospitals and other health institutions to manufacture new devices, or modify existing devices, to meet specific clinical needs for their own patients – from specialist software that supports precise drug dosing to communication aids designed to help patients with a communication impairment.

The updated leading practice guidelines will provide health institutions clearer direction on when and how the Health Institution Exemption can be applied in practice. This aligns

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with the UK government's missions, including the 10 Year Health Plan for England and the Life Sciences Sector Plan, and their focus on the role of technology in health services.

The update follows a recent survey of health institutions and sets out five core principles that they should follow: maintaining quality management systems, ensuring device traceability, meeting the essential requirements, keeping technical documentation, and ongoing monitoring of how devices perform. The guidance also includes practical, everyday scenarios to help medical physicists, clinical engineers and other healthcare professionals understand when the Health Institution Exemption applies. Read the full article for more information.

MHRA host workshop to improve Patient Information Leaflets

This month the MHRA hosted a workshop as part of an ongoing project to explore how patient information offered to UK patients could be improved in the future.

Attendees at the workshop included Patient Safety Commissioner Henrietta Hughes along with external colleagues, patient groups and industry representatives leading the electronic Patient Information (ePI) taskforce.

The aim was to listen and understand how digital solutions could be utilised to improve use and accessibility of Patient Information Leaflets (PILs), while ensuring patient safety is maintained. It was also vital to understand how patients interact with information about their medicinal products in today's environment and how to ensure that it meets the needs of a population with diverse requirements.

The MHRA want to not only improve but really make a difference to the future of patient information leaflets. The workshop will help to inform policy direction and an action plan that can be taken forward into 2026.

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