Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

July 2026

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

Contents

Drug Safety Update

Botulinum toxin type A products: updated warnings regarding risk of iatrogenic botulism — Page 2

Cases of iatrogenic botulism have been reported following the therapeutic or cosmetic use of botulinum toxin containing products where the toxin's effect extends beyond the area of treatment. Patients should seek immediate medical advice if they experience signs and symptoms.

Drug Safety Update

Domperidone: new contraindication in patients with phaeochromocytoma due to the risk of severe hypertension — Page 4

The product information has been updated for all domperidone products, to include a contraindication for patients with confirmed or suspected phaeochromocytoma (a rare tumour of the adrenal gland), due to the risk of episodes of severe hypertension.

Letters, Recalls and Device Notifications — Page 5

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

How to Report — Page 7

Report suspected drug reactions and device incidents on a Yellow Card

To subscribe to monthly email alerts of MHRA Safety Roundup scan the QR code

News Roundup

- Immune checkpoint inhibitors: product information updated to include myocarditis-myositis-myasthenia gravis overlap syndrome — Page 7
- Bladder anticholinergics: review of risk of dementia

Botulinum toxin type A products: updated warnings regarding risk of iatrogenic botulism

Access the full article

Specialisms: *cosmetic surgery, Dentistry, Dermatology, Neurology and Urology and nephrology*

Summary

Cases of iatrogenic botulism have been reported following the therapeutic or cosmetic use of botulinum toxin containing products where the toxin's effect extends beyond the area of treatment. Botulism caused by botulinum toxin is rare but can be life threatening. Symptoms can take up to four weeks to develop and may typically include difficulty breathing or shortness of breath, difficulty swallowing, talking or slurred speech and muscle weakness. In severe cases, patients may require mechanical ventilation and intensive care treatment.

Key Advice for Healthcare Professionals:

- cases of iatrogenic botulism, (botulism caused by a therapeutic or cosmetic procedure) following use of botulinum toxin containing products have been rarely reported
- symptoms of iatrogenic botulism typically occur between 4 and 8 days but can take up to 4 weeks to develop following treatment with botulinum toxin
- risks of botulism may be increased in patients with underlying disorders that may predispose them, the use of high-doses of botulinum toxin, using a product off-label

To subscribe to monthly email alerts of MHRA Safety Roundup scan the QR code

or administering a product into unapproved sites, or in the use of counterfeit or unauthorised products

- the product information for these products is being updated to include a warning of iatrogenic botulism
- advise new and existing patients to be aware of symptoms of botulism including, severe drooping of the upper eye lids difficulty breathing, speaking (slurred speech) and difficulty swallowing. This is a medical emergency and patients should be advised to seek immediate medical help
- if you suspect your patient may have botulism, follow the UK Health Security Agency advice on the clinical management of iatrogenic botulism
- check that the botulinum toxin product is authorised for use and follow the product specific guidance in the product information for administration, dose and indication
- prescribers should ensure that anyone they direct to administer the product, including practitioners who may use it for cosmetic purposes, follow the directions on the prescription and that they are familiar with this Drug Safety Update and the actions to be taken
- report any suspected side effects or complications via the Yellow Card scheme

Key Advice for Healthcare Professionals to Provide to Patients:

- treatment with botulinum toxin has in rare cases caused botulism and other serious adverse reactions and symptoms which can occur up to 4 weeks following treatment
- if you experience any symptoms of botulism following treatment with botulinum toxin including difficulty swallowing, slurred speech and breathing difficulty, seek immediate medical attention via emergency services
- your administering practitioner (who should be appropriately trained and qualified) should verify that the product being used is licensed for use in the UK. Use of unlicensed or counterfeit products can significantly increase your risk of adverse reactions. Refer to the NHS advice for information on choosing your administering practitioner. Please refer to the following links for a list of registered independent healthcare providers for England (private hospitals and clinics) Northern Ireland, Wales and Scotland
- report any suspected side effects following botulinum toxin to the Yellow Card scheme

To subscribe to monthly email alerts of MHRA Safety Roundup scan the QR code

Domperidone: new contraindication in patients with phaeochromocytoma due to the risk of severe hypertension

Access the full article

Specialisms: *Cardiovascular disease and lipidology, Emergency medicine, Endocrinology, diabetology and metabolism, General practice, GI, hepatology and pancreatic disorders, Haematology and oncology and Pharmacy*

Summary

Domperidone is a dopamine antagonist with anti-emetic properties. It is licensed for use in adults and in children 12 years and above. Phaeochromocytomas are rare tumours of the adrenal gland and are often diagnosed through incidental imaging.

A recent European review of safety data for domperidone identified an association between domperidone and episodes of severe hypertension in patients with phaeochromocytoma following a small number of reports of this event. As a result, recommendations have been made to update the product information to include a contraindication for use of domperidone in patients with phaeochromocytoma due to the risk of severe hypertension.

Key Advice for Healthcare Professionals:

- a small number of reports have been received relating to severe episodes of hypertension in patients with phaeochromocytoma (a rare tumour of the adrenal gland) following administration of domperidone
- domperidone is now contraindicated in patients with confirmed or suspected phaeochromocytoma
- patients with confirmed or suspected phaeochromocytoma should stop taking domperidone immediately and be switched to an alternative treatment
- be aware that administration of domperidone can unmask phaeochromocytomas. If a patient taking domperidone has an episode of severe hypertension, consider further investigations for phaeochromocytoma
- domperidone should be used at the lowest effective dose for the shortest possible duration and maximum treatment duration should not usually exceed 1 week
- for patients receiving palliative care, an individual benefit risk decision on treatment should be made in discussion with the patient

- report suspected adverse drug reactions associated with domperidone via the Yellow Card scheme

Key Advice for Healthcare Professionals to Provide to Patients:

- stop taking domperidone immediately if you have been diagnosed with phaeochromocytoma (a rare tumour of the adrenal gland) by your doctor. Speak to your doctor or pharmacist about alternative treatment options
- seek medical attention immediately if you experience symptoms of severe high blood pressure. Symptoms can include, but are not limited to: persistent headache, blurred vision, shortness of breath and chest pain
- report suspected adverse drug reactions associated with domperidone via the Yellow Card scheme

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

Direct Healthcare Professional Communications

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

- Stoboclo▼ 60mg/ml pre-filled syringe (Denosumab) Interim supply of Irish Stock to Mitigate Supply Disruption
- BEROMUN® 1mg, Powder for solution for infusion (Tasonermin- EU license number: EU/1/99/097/001): Interim Supply of German Stock to Mitigate Supply Disruption
- Paliperidone STADA 75mg prolonged-release suspension for injection (paliperidone); Paliperidone STADA 100mg prolonged-release suspension for injection (paliperidone); Paliperidone STADA 150mg prolonged-release suspension for injection (paliperidone) - Interim supply of foreign-language stock to mitigate Market Shortage
- Avacopan Vifor, previously known as Tavneos (avacopan)▼: Updated requirements for liver monitoring and stopping rules to mitigate risk of drug-induced liver injury and vanishing bile duct syndrome
- Pedea 5 mg/ml solution for injection [PLGB 15266/0024]: Interim Supply of Multi-Language European Stock Including English-Language Product Information to Mitigate Supply Disruption
- Notification of an out of specification result in a single batch of of Fivasa (mesalazine) 400 mg modified-release tablets

To subscribe to monthly email alerts of MHRA Safety Roundup scan the QR code

Medicine Recalls and Notifications

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

Class 2 Medicines Recall: Beckton Dickson UK Ltd, ChloraPrep 1mL applicator, EL(26)A/34. Issued 13 July 2026.

Becton Dickinson UK Ltd are recalling batches of ChloraPrep 2% w/v / 70% v/v cutaneous solution 1mL applicators due to a potential breach of sterility in the packaging process.

Class 2 Medicines Recall: Bristol Laboratories Limited, Phenoxymethylpenicillin 250 mg/5ml Sugar free Oral Solution BP, EL(26)A/33. Issued 9 July 2026.

Bristol Laboratories Limited is recalling one batch (7124002) of Phenoxymethylpenicillin 250 mg/5 ml Oral Solution Sugar Free due to product labelling issues.

Class 4 Medicines Defect Notification: Neuraxpharm UK Ltd, Tuzulby prolonged-release chewable tablets, EL(26)A/36. Issued 23 July 2026.

Neuraxpharm UK Ltd has informed the MHRA of missing safety information in the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) for certain batches of Tuzulby prolonged release 20mg, 30mg and 40mg chewable tablets.

Class 4 Medicines Defect Notification: Macarthys Laboratories Ltd T/A Martindale Pharma, Xaggitin XL Prolonged-release Tablets, EL(26)A/35. Issued 20 July 2026.

Macarthys Laboratories Ltd T/A Martindale Pharma has notified the MHRA of a manufacturing issue impacting several batches of Xaggitin XL Prolonged-release Tablets, due to the occurrence of incorrect tablet counts in the bottles.

Medical Device Field Safety Notices

Find recently published Field Safety Notices

To subscribe to monthly email alerts of MHRA Safety Roundup scan the QR code

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

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

Immune checkpoint inhibitors: product information updated to include myocarditis-myositis-myasthenia gravis overlap syndrome

Myocarditis, myositis and myasthenia gravis are recognised immune-related adverse reactions which occur with immune checkpoint inhibitors. They can occur separately or at the same time, known as myocarditis-myositis-myasthenia gravis overlap syndrome

To subscribe to monthly email alerts of MHRA Safety Roundup scan the QR code

(involving two or all three conditions) and this is associated with a high risk of morbidity and mortality.

The product information for avelumab (Bavencio), ipilimumab (Yervoy), nivolumab (Opdivo), nivolumab with relatlimab (Opdualag) and pembrolizumab (Keytruda) has been updated to include this adverse reaction, together with advice on when treatment should be withheld or permanently discontinued. The latest approved product information for each product is available on the MHRA products website.

Patients should be advised to seek advice from their doctor immediately if they develop a combination of symptoms of myocarditis (which may cause chest pain, shortness of breath, and an irregular and/or rapid heartbeat), myositis (which may cause muscle pain and weakness), and myasthenia gravis (in which muscles become weak and tire easily).

Healthcare professionals are reminded that immune-related adverse reactions affecting more than one body system can occur simultaneously. Furthermore, early recognition and aggressive management are essential to reduce the morbidity and risk of mortality associated with myocarditis-myositis-myasthenia gravis overlap syndrome.

Bladder anticholinergics: review of risk of dementia

In recent years, a growing number of studies have been published looking at whether people who take anticholinergic medicines have a higher risk of dementia. Many of these studies have looked at the risk of dementia associated with bladder anticholinergics. The Commission on Human Medicines recommended a review of the available evidence examining a possible link between use of bladder anticholinergics and the onset of dementia.

The overall findings of the review are that the available evidence is not sufficient to confirm that use of bladder anticholinergic medicines directly increases the risk of developing dementia; however, the limitations of these studies mean that a small increased risk cannot be ruled out completely. Further details of the evidence considered, and the conclusions reached are available through a Public Assessment report.

Patients should be advised to discuss any concerns with their healthcare professional; they should not stop taking their medicine without medical advice. In line with clinical guidance, healthcare professionals should aim to limit the number of anticholinergic medicines older people take and use the lowest dose to control their condition.

To subscribe to monthly email alerts of MHRA Safety Roundup visit our sign up page

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