Medicines & Healthcare products Regulatory Agency

DRUG SAFETY UPDATE (DSU)

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

Specialisms: Cosmetic Surgery, Dentistry, Dermatology, Neurology, 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. Patients should seek immediate medical advice if they experience any of the signs and symptoms consistent with the spread of toxin or if they experience difficulties with swallowing, speech or breathing.

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 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

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

Background

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.

Serious adverse reactions due to the distant spread of toxin have been closely monitored and have been reflected in the product information since 2007. The Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) for all UK-authorised botulinum toxin type A containing products will be further strengthened in the coming months to highlight the risk of iatrogenic botulism and to advise patients to seek immediate medical advice if they experience any signs or symptoms consistent with the spread of botulinum toxin effect or iatrogenic botulism.

The risk of adverse reactions from the spread of toxin or botulism may be increased in patients:

- Who have underlying conditions and comorbidities (underlying neurological disorders, or a history of dysphagia or aspiration)
- Where high doses of botulinum toxin are used
- Where a product is used outside of its licensed indications (off-label) and administered into unapproved sites
- Where a counterfeit or unauthorised botulinum toxin containing product is used

Healthcare professionals who are managing patients with suspected botulism should follow the UK Health Security Agency advice on the clinical management of iatrogenic botulism. Treatment can vary and may include the use of botulinum antitoxin to neutralise circulating toxin, supportive therapy and/or treatment of specific symptoms. Recovery will depend on the severity of symptoms.

In patients presenting with only localised side effects where administration of botulinum antitoxin is not indicated, it may be necessary to monitor for further progression of symptoms and presentation of systemic neurological symptoms.

Botulinum toxin containing products

Botulinum toxins are prescription only medicines in the UK and should only be sold or supplied in accordance with a prescription given by an appropriate prescriber. There are a number of authorised products containing botulinum toxin which have been granted a marketing authorisation for use in the UK. Botulinum toxin products authorised for use in the UK and their respective product information (SmPC and PIL) can be found on the MHRA website.

The licensed indications for botulinum containing products vary by product and include neurologic disorders (e.g. focal spasticity, some types of spasms and chronic migraine), bladder disorders (e.g. overactive bladder), severe sweating of the axillae (hyperhidrosis) and for the temporary improvement in the appearance of facial lines where their severity has an important psychological effect on the patient.

The product information contains the recommendations for use of each botulinum toxin containing product, including the authorised indications, administration sites and specific dosing guidance. Units of botulinum toxin are not interchangeable from one product to another.

Use of unlicensed botulinum toxin products

The MHRA are cracking down on the illegal sale and supply of unlicensed and counterfeit botulinum toxins. Buying botulinum toxins from illegal suppliers, including from within the UK or importing them from abroad, significantly increases the risk of getting a product which is either falsified or not licensed for use in the UK. This means that there are no safeguards to ensure products meet the MHRA's standards for quality and safety. Use of these products can significantly increase your risk of adverse reactions and can endanger the health of the people who take them.

The MHRA's Criminal Enforcement Unit has launched a number of investigations linked to the use of unlicensed botulinum toxin products following a spike in hospital admissions seen last year.

Reporting advice

Healthcare professionals, non-medical practitioners, 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

Stakeholder engagement:

- JCCP
- SaveFace
- NHS England Patient Safety team, Specialist Pharmacy Service and Devolved Administrations
- UKHSA

Article citation: MHRA Drug Safety Update volume 19, issue 2: July 2026: 1