Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

November 2026

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

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There have been several reports internationally of deaths of patients with Duchenne muscular dystrophy (DMD) while being treated with Duvyzat® (givinostat). Following a review of these cases and associated evidence, the MHRA has proposed updates to the product information.

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Duvyzat®▼ (givinostat): interim advice on risk mitigation measures following reports of deaths of patients while taking givinostat

Access the full article

Specialisms: *Neurology, Cardiovascular Disease and Lipidology, Paediatrics and Neonatology, Pharmacy*

Summary

There have been several reports internationally of deaths of patients with Duchenne muscular dystrophy (DMD) while being treated with Duvyzat® (givinostat). Following a review of these cases and associated evidence, the MHRA has proposed updates to the product information. Interim monitoring advice is being provided by the MHRA based on these proposals, pending independent review and finalisation of the MHRA's position.

Key Advice for Healthcare Professionals:

- continue to refrain from using Duvyzat® in patients at increased risk for ventricular arrhythmias, such as those with congenital long QT syndrome, coronary artery disease, electrolyte disturbances, or those taking other medicines known to cause QT prolongation
- continue to follow the Duchenne Care UK (North Star) clinical guidance, which provides information on cardiac monitoring and clinical monitoring
- obtain ECGs before initiating treatment, within 2-4 weeks after starting givinostat, and then every 6 months thereafter, in line with Duchenne Care UK (North Star) clinical guidance. The guidance also provides advice on thresholds for cardiology input. Additionally, the MHRA advises that 24-hour ambulatory ECG monitoring should also be undertaken at baseline, and repeated when the patient is on a stable dose of medication
- the MHRA also advises that serum electrolytes (including potassium, magnesium and calcium) should be monitored at the same frequency as haematological bloods every 2 weeks for the first 2 months of treatment, at month 3, and then every 3 months thereafter

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- Duvyzat®▼ (givinostat) is a black triangle medicine and is subject to additional monitoring. Report ALL suspected adverse drug reactions associated with Duvyzat® on a Yellow Card

Key Advice for Healthcare Professionals to Provide to Patients:

- a small number of deaths have been reported outside the UK in people with Duchenne muscular dystrophy while taking Duvyzat® (givinostat). No deaths have been reported in the UK. The MHRA has reviewed the available information and is providing interim advice on the frequency of monitoring (such as ECGs or blood tests), pending finalisation of an independent review
- the proposed changes to monitoring aim to ensure that Duvyzat® remains as safe as possible for all Duchenne muscular dystrophy patients
- continue taking Duvyzat® as prescribed and attend all appointments. Tell your doctor about any additional medications you are taking or if they change
- speak to your specialist Duchenne's team if you have any concerns about your treatment
- Duvyzat®▼ (givinostat) is a black triangle medicine and is subject to additional monitoring. Report ALL suspected adverse drug reactions associated with Duvyzat® on a Yellow Card

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

Direct Healthcare Professional Communications

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

- ChloraPrep 2% w/v / 70% v/v cutaneous solution - 1 mL presentation - chlorhexidine digluconate / isopropyl alcohol: Interim Supply of US Stock to Mitigate Supply Disruption in the UK
- ChloraPrep 2% w/v / 70% v/v cutaneous solution - 1.5 mL presentation - chlorhexidine digluconate / isopropyl alcohol: Interim Supply of US Stock to Mitigate Supply Disruption in the UK
- Esmolol hydrochloride; Brevibloc Premixed 10mg/ml Solution for Infusion

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- Accusol 35 Solution for haemofiltration, haemodialysis and haemodiafiltration, PL 44204/0001 - Supply of Accusol 35 K0, Solution for haemofiltration, haemodialysis and haemodiafiltration for continuous patient supply
- Accusol 35 Potassium 2 mmol/L, Solution for haemofiltration, haemodialysis and haemodiafiltration PL 44204/0002 - Supply of Accusol 35 Potassium 2 mmol/L, Solution for haemofiltration, haemodialysis and haemodiafiltration for continuous patient supply
- Truxima 500mg vial (rituximab) - Interim supply of Irish Stock to Mitigate Supply Disruption
- Truxima 100mg vial (rituximab) - Interim supply of French Stock to Mitigate Supply Disruption
- PEDMARQSI (sodium thiosulfate) 80 mg/mL solution for infusion: requirement for visual inspection of each vial upon receipt, before administration and mandatory use of a filter (pre-administration filtration or in-line filtration)

Medicine Recalls and Notifications

In October and November 2026 recalls and notifications for medicines were issued on:

Class 2 Medicines Recall: Quadrant Pharmaceuticals Limited (Parallel Import), Brintellix 5 mg film-coated tablets, EL(26)A/49. Issued 24 November 2026.

Quadrant Pharmaceuticals Ltd is recalling one batch of Brintellix 5 mg film-coated tablets (mislabelled as 10 mg tablets) due to a labelling error with the product strength impacting an unknown number of units.

Class 2 Medicines Recall: Accord-UK Ltd, Lercanidipine Hydrochloride 10mg Film-Coated Tablets, EL(26)A/45. Issued 29 October 2026.

Accord-UK Ltd is recalling one batch of Lercanidipine Hydrochloride 10mg Tablets due to a packaging mix-up involving the incorrect strength.

Class 2 Medicines Recall: Advanz Pharma Limited, Mynzepli 40 mg/mL solution for injection in pre-filled syringe, EL(26)A/44. Issued 29 October 2026.

Advanz Pharma Limited are recalling specified batches of Mynzepli 40 mg/mL solution for injection in pre-filled syringe as a precautionary measure.

Class 3 Medicines Recall: Aspire Pharma Limited, Tropicamide 1% Eye Drops, solution in single dose containers 20 x 0.5ml , EL(26)A/47. Issued 5 November 2026.

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Aspire Pharma Ltd is recalling specific batches of Tropicamide 1% Eye Drops, solution in single dose containers 0.5ml x 20, due to them being labelled with the incorrect expiry date. The correct expiry date for these batches should be 31/10/2026.

Class 3 Medicines Recall: Mercury Pharmaceuticals Limited, Bexarotene 75 mg soft capsules, EL(26)A/51. Issued 25 November 2026.

Mercury Pharmaceuticals Limited is recalling Bexarotene 75 mg Soft Capsules, batch 5GJ0551, as a precautionary measure following the identification of several capsules with black/blue spots during additional Acceptable Quality Limit (AQL) testing at the pre-wholesaler's site.

Class 4 Medicines Defect Notification: Sandoz Limited, Co-Amoxiclav powder for oral suspension 250/62.5 mg/5mL, EL(26)A/46. Issued 5 November 2026.

Sandoz Limited have informed the MHRA of errors in the dosing table in the Summary of Product Characteristics (SmPC) for Co-amoxiclav 250/62.5 mg/5 ml Powder for Oral Suspension.

Class 4 Medicines Defect Notification: Star Pharmaceuticals Ltd, Enalapril maleate/ Hydrochlorothiazide 20 mg/12.5 mg Tablets, EL(26)A/48. Issued 12 November 2026.

Star Pharmaceuticals Limited have informed the MHRA of a typographical error on the strength of hydrochlorothiazide printed on the front face of the carton which incorrectly states "12. mg" instead of "12.5 mg".

Class 4 Medicines Defect Notification: Atnahs Pharma UK Limited, Toradol 30 mg/mL Solution for Injection, EL(26)A/50. Issued 24 November 2026.

Atnahs Pharma UK Ltd has informed the MHRA that safety information relating to gastrointestinal anastomotic leakage was omitted from the Patient Information Leaflets (PILs) supplied with certain batches of Toradol 30 mg/mL solution for injection.

Class 4 Medicines Defect Notification: Takeda UK Limited, PROSTAP PD DCS 1.88 mg powder and solvent for prolonged-release suspension for injection in pre-filled syringe, EL(26)A/52. Issued 25 November 2026.

Takeda UK Limited has identified an error in the administration instructions and labelling for PROSTAP PD DCS 1.88 mg. The product should only be administered by subcutaneous injection.

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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

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

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News Roundup

GLP-1 medicine guidance updates

The product information for tirzepatide (Mounjaro) has been updated to reflect the results of a new lactation study. The study has shown that tirzepatide passes into breast milk in very low amounts. As tirzepatide is a protein-based medicine, any tirzepatide present in breast milk is expected to be broken down and not absorbed by a breastfed child.

A new GLP-1 receptor agonist, orforglipron (Foundayo), has been licensed. Unlike other GLP-1s, orforglipron is not a protein- based medicine and can interact with other medicines.

The GLP-1 medicines for weight loss and diabetes: what you need to know guidance page has been updated with key safety information about orforglipron and changes to the product information for tirzepatide.

Voxelotor: withdrawal of marketing authorisation

The marketing authorisation for voxelotor (Oxbryta) has been withdrawn in the UK.

Voxelotor was previously withdrawn from the UK and worldwide market in September 2024 while a review of the benefits and risks was carried out. Healthcare professionals were informed at the time (Direct Healthcare Professional Communication).

The review was triggered by data suggesting an unfavourable imbalance in the number of vaso-occlusive crises (sudden pain crises experienced by those with sickle cell disease) and fatal events in patients treated with voxelotor. Following review, the data suggests the benefits of the product no longer outweigh the risks in the indicated population, and the marketing authorisation has been withdrawn.

Voxelotor was authorised in the UK for the treatment of haemolytic anaemia due to sickle cell disease in adults and paediatric patients 12 years of age and older as monotherapy or in combination with hydroxycarbamide.

Voxelotor has not been available in the UK since September 2024, and therefore there are no specific actions for patients or healthcare professionals following the withdrawal of the marketing authorisation.

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

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