NHS Circular: MSAN (2025) 21

Chief Medical Officer Directorate Pharmacy and Medicines Division



07 May 2025

Medicine Supply Alert Notice

Diazepam 10mg/2ml solution for injection ampoules

Priority: Level 2*

Valid until: October 2025

Issue

- 1. Diazepam 10mg/2ml solution for injection ampoules are currently in very limited supply and are expected to be out of stock from early May until late July 2025.
- 2. To help manage this shortage, the Medicines and Healthcare products Regulatory Agency (MHRA) has granted a six-month extension to the expiry date of a specific batch (BN 217019), which was originally set to expire in April 2025, and now is extended to October 2025.
- 3. Licensed stock should be prioritised for ambulance services including private ambulance providers.
- 4. Health Boards and the Scottish Ambulance Service (SAS) are advised to seek mutual aid for stock holdings, especially in cases where surplus unused stock is available.
- 5. Alternative benzodiazepines, including intravenous and buccal midazolam, intravenous lorazepam, and rectal diazepam, remain available and can support a full increase in demand.
- 6. Unlicensed supplies of diazepam 10mg/2ml solution for injection ampoules can be sourced, though lead times may vary.

Advice and Actions

- 7. Health Board pharmacy procurement teams, the SAS and other response providers should:
 - review local stock holdings of diazepam 10mg/2ml solution for injection ampoules;
 - identify any stock subject to the shelf-life extension and where suitable stock is identified
 extend the shelf life in line with your local policies ensuring the batch number is still visible
 (refer to Additional Information section);
 - conserve all remaining licensed stock of diazepam 10mg/2ml solution for injection ampoules for key responders until the shortage has resolved;
 - consider the use of mutual aid;
 - consider the use of alternative benzodiazepine preparations (refer to Additional Information section);
 - consider ordering unlicensed imports of diazepam 10mg/2ml solution for injection ampoules, where use of alternative benzodiazepines is considered inappropriate;
 - review and update local Health Board guidelines as needed, including the use of alternative agents; and
 - ensure all impacted clinical areas are made aware of this issue and of any relevant changes.

^{*}https://www.nss.nhs.scot/media/1842/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.pdf

Additional Information

Clinical information

- 8. Diazepam is an anxiolytic, anticonvulsant and central muscle-relaxant. It is licensed:
 - to relieve anxiety and provide sedation in severe acute anxiety or agitation and for the management of agitation associated with delirium tremens
 - to relieve acute muscle spasm and tetanus
 - for treating acute convulsions including status epilepticus, also convulsions due to poisoning and febrile convulsions
 - as an adjunct during endoscopy, in dentistry, surgery, radiology
 - In cardiac catheterisation, cardioversion used pre-operatively to relieve anxiety, provide sedation, light anaesthesia and anterograde amnesia

Supply Information

- 9. The following alterative benzodiazepines remain available and can support a full uplift in supply:
 - Diazepam 10mg/2.5ml rectal solution tube
 - Midazolam oromucosal solution
 - Lorazepam 4mg/ml solution for injection ampoules
 - Midazolam 5mg/5ml solution for injection ampoules
 - Midazolam 10mg/2ml solution for injection ampoules

Details of Expiry Date Extension

10. The following batch of diazepam 10mg/2ml solution for injection ampoules has been granted an expiry extension by the MHRA:

LOT	Original Expiry Date	Extended Expiry date
BN 217019	April 2025	October 2025

11. Please note that when the MHRA quotes a shelf-life extension of 42 months, it includes the original shelf life of 36 months from when the product was produced, plus an additional 6 months, making a total of 42 months.

Guidance on ordering and prescribing unlicensed imports

- 12. The following specialist importers have confirmed they can source diazepam 10mg/2ml solution for injection ampoules (please note there may be other companies that can also source supplies):
 - Qmed Pharma
 - Mawdslevs
- 13. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Health Board or local governance procedures. Unlicensed imports do not undergo any

central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes. Please see the links below for further information:

- <u>The supply of unlicensed medicinal products</u>, Medicines and Healthcare products Regulatory Agency (MHRA)
- <u>Professional Guidance for the Procurement and Supply of Specials</u>, Royal Pharmaceutical Society
- Prescribing unlicensed medicines, General Medical Council (GMC).

Links to further information

- BNF Diazepam
- SmPCs: Diazepam products
- BNF Lorazepam
- SmPC Lorazepam
- BNF Midazolam
- SmPCs: Midazolam products
- NICE Guideline NG217 Epilepsies in children, young people and adults
- The Misuse of Drugs (England and Wales and Scotland) (Amendment) (No. 2) Regulations 2023

Specialist Pharmacy Service (SPS) website

- 14. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the SPS website. Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
- 15. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

Enquiries

16. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to PharmacyTeam@gov.scot (primary care) or NSS.NHSSMedicineShortages@nhs.scot (secondary care).