Medicines & Healthcare products Regulatory Agency

Drug Safety Update

Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

Volume 18 Issue 5 December 2024

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The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for ensuring that medicines and medical devices work and are acceptably safe.

The Commission on Human Medicines gives independent advice to ministers about the safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.

NICE accredited
www.nice.org.uk/accreditation

NICE has accredited the process used by the MHRA to produce Drug Safety Update guidance. More information on accreditation can be viewed on the NICE website.

To subscribe to monthly email alerts of Drug Safety Update see: https://www.gov.uk/drug-safety-update

This month our Drug Safety Update provides a summary of recent letters and notifications sent to healthcare professionals about medicines and medical devices.

If you have been forwarded this issue of Drug Safety Update, subscribe directly via our website.

Letters and medicine recalls sent to healthcare professionals in November 2024

A summary of recent letters and notifications sent to healthcare professionals about medicines and medical devices.

Letters

In November 2024, the following letters were sent or provided to relevant healthcare professionals:

- Welireg▼ (belzutifan) Patient alert cards
- COMIRNATY® ▼ JN.1, 30 micrograms/dose dispersion for injection in pre-filled syringe (glass) (PLGB 53632/0046) - Supply of Refrigerated Stock in EU approved artwork for Private Market
- Movymia 20 micrograms/80 microliters solution for injection▼ (teriparatide):Interim Supply of French Stock to Mitigate Supply Disruption
- IMVANEX suspension for injection, Interim Supply of EU Stock to Mitigate Supply Disruption

Medicine Recalls and Notifications

In November 2024, recalls and notifications for medicines were issued on:

Class 3 Medicines Recall: Syri Limited, T/A SyriMed, Baclofen 10mg/5ml Oral Solution, EL(24)A/56. Issued 25 November 2024. Syri Limited, T/A SyriMed is recalling this batch of product as a precautionary measure due to crystallisation observed over time in the oral solution.

Company led medicines recall: Leeds Trading Company LTC Ltd T/A LTC Healthcare, EXS Delay Spray Plus, CLMR(24)A/01. Issued 13 November 2024. LTC Healthcare has informed the MHRA that they have been selling a medicinal product containing lidocaine without authorisation from the MHRA.

Class 4 Medicines Defect Information: Ennogen Healthcare Limited, Zoledronic Acid Ennogen 4mg/5ml concentrate for solution for infusion, EL (24)A/53. Issued 7 November 2024. Ennogen Healthcare Limited has identified that action had not been taken to ensure the Patient Reminder Card (PRC) was distributed alongside the packs of product as part of the approved Additional Risk Minimisation Measures (RMM).

Class 4 Medicines Defect Information: Viatris UK Healthcare Ltd, Omeprazole 40 mg Powder for solution for infusion, EL(24)A/54. Issued 12 November 2024. Generics (U.K.) Limited has informed the MHRA that the Patient Information Leaflet (PIL) packaged in

specific batches of Omeprazole 40 mg Powder for solution for infusion do not contain the most up to date safety information.

Class 4 Medicines Defect Information: Takeda UK Limited, Entyvio 108mg solution for injection in pre-filled syringe, EL(24)A/55. Issued 18 November 2024. Takeda UK Limited has informed the MHRA that there is an error in the Patient Information Leaflet for specified batches of Entyvio 108mg pre-filled syringes.

Class 4 Medicines Defect Information: Morningside Healthcare Limited, Tramadol Hydrochloride 50 mg capsules & Tramadol Hydrochloride Morningside 50 mg Prolonged-Release capsules, EL(24)A/57. Issued 27 November 2024. Morningside Healthcare Limited has informed the MHRA of a packaging issue identified in batch MRA2303 of Tramadol Hydrochloride Morningside 50 mg Prolonged-Release Capsules and batch MRF2301 of Tramadol Hydrochloride 50 mg Capsules.

Class 4 Medicines Defect Information: Strides Pharma UK Ltd, Liothyronine Sodium 5 & 20 micrograms Tablets, EL(24)A/58. Issued on 28 November 2024. Strides Pharma UK Ltd has informed MHRA of an error in the patient information leaflet (PIL) for Liothyronine Sodium 20 micrograms Tablets and Liothyronine Sodium 5 micrograms Tablets.