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 17 Issue 8 March 2024

Contents

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 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.

© Crown Copyright 2024

Letters and medicine recalls sent to healthcare professionals in February 2023

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

Letters

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

- Refixia® ▼ 3000 IU powder and solvent for solution for injection (nonacog beta pegol): Carton printing error
- Ebglyss ▼ 250 mg solution for injection in pre-filled pen and prefilled syringe (lebrikizumab): Interim Supply of Great Britain Stock to Mitigate Supply Disruption (Note: Black Triangle med)
- Pseudoephedrine – Risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Medicine Recalls and Notifications

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

Class 4 Medicines Defect Information: Exeltis UK Limited, Gepretix 100mg Capsules, EL (24)A/04. Issued: 1 February 2024. Exeltis UK Limited has informed the MHRA regarding an inconsistency in the Patient Information Leaflet (PIL) packaged in cartons of the specified batches of Gepretix 100mg capsules.

Class 3 Medicines Recall: Torrent Pharma (UK) Limited, Ramipril 1.25mg tablets, EL(24)A/05. Issued: 13 February 2024. Torrent Pharma (UK) Limited is recalling batches of Ramipril 1.25mg tablets as a precautionary measure due to these batches having a low assay and high related substances test results after their release to the market.

Class 2 Medicines Recall: Novartis Pharmaceuticals UK Limited, Adakveo 10 mg/ml concentrate for solution for infusion, EL(24)A/06. Issued: 21 February 2024. Novartis Pharmaceuticals UK Limited is recalling Adakveo 10 mg/ml concentrate for solution for infusion, batch number SJFN5, due to the benefit-risk balance of Adakveo no longer being considered favourable by the MHRA. This is because the Phase III study (STAND) of Adakveo in sickle cell disease patients with vaso-occlusive crises did not confirm its clinical benefit. As a consequence, the conditional marketing authorisation in the UK is being revoked.

© Crown Copyright 2024

Class 4 Medicines Defect Information: Orifarm UK Ltd, Concerta XL 18mg & 36 mg prolonged release tablets, EL (24)A/07. Issued: 26 February 2024. Orifarm UK has informed the MHRA of an error with the Patient Information Leaflet (PIL) packaged within the parallel import packs of the above batches of Concerta XL 18mg and 36mg prolonged release tablets. A section of the product side effects containing the serious side effects has been added to paragraph 3 in error however this should be part of paragraph 4. All other sections of the PIL are unaffected.

Medical Device Safety Information

We recently published Device Safety Information pages on the following topics:

MAGEC X System, NuVasive Specialized Orthopedics (NSO): UK suspension lifted, (DSI/2024/002). Issued: 12 March 2024. The MHRA has conducted a thorough assessment of technical and biological safety information provided by NSO and is satisfied that the modified MAGEC X system can now be used in the UK. NSO has agreed to meet a set of conditions to monitor the long-term safety and performance of the device. All previous generations of the MAGEC system (MAGEC 1,1.5, 2B) remain suspended in the UK and should not be implanted. For additional information, please refer to the Device Safety Information page.

Paclitaxel coated devices (PCD) used in the treatment of peripheral arterial disease: update to previous MHRA guidance on use. Where indicated, PCD can be considered as a treatment option for both critical limb ischaemia (CLI) and intermittent claudication (IC) patients. (DSI/2024/001). Issued: 5 February 2024. The MHRA has updated our previous guidance (DSI/2022/003) on the use of paclitaxel coated devices (PCD) in the treatment of peripheral arterial disease (PAD). The MHRA conducted an extensive review of the most recent published literature and sought the advice of the Interim Devices Working Group (IDWG) and invited experts. Following this review, the MHRA has updated its previous advice on PCD to remove restrictions on indication, dose, and repeated exposure. For additional information, please refer to the Device Safety Information page.

Article citation: Drug Safety Update Volume 17, issue 8, March 2024: 1.

© Crown Copyright 2024