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

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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.

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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.

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This month on page 2 we summarise recent advice relating to COVID-19 vaccines and medicines published since the January 2023 issue of Drug Safety Update. And on page 3, we include recent letters, recalls, 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.

COVID-19 vaccines and medicines: updates for February 2023

Summaries of Yellow Card reporting

We continue to publish the summaries of the Yellow Card reporting for the COVID-19 vaccines being used in the UK. The report summarises information received via the Yellow Card scheme and includes other data such as usage of COVID-19 vaccines and relevant epidemiological data. The report is updated regularly to include other safety investigations carried out by the MHRA under the COVID-19 Vaccine Surveillance Strategy.

The MHRA has updated the format of the summary of Yellow Card reporting to focus on the bivalent coronavirus vaccines being administered as part of the autumn booster campaign. Information on monovalent vaccines used in the previous primary and initial booster campaign will remain available as a record on the government website. Yellow Card reports received via the scheme across all COVID-19 vaccines will be updated and reflected in the COVID-19 vaccine reports.

Other recent MHRA updates on Coronavirus vaccines and medicines:

We have also recently:

- updated the SmPC and PIL documents for the COVID-19 Vaccine AstraZeneca to add tinnitus as an uncommon side effect
- added a new, age-appropriate presentation of product information for the bivalent version of the vaccine Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose
- authorised a new version of the Moderna 'bivalent' Covid vaccine (Spikevax) that targets both the original strain of SARS-CoV-2 and the Omicron BA.4 and BA.5 sub-variants after finding it meets the MHRA's acceptable standards of safety, quality and effectiveness

See guidance on COVID-19 for all our latest information, including after publication of this article.

We previously included summaries of latest COVID-19 information, including in the November 2022, December 2022 and January 2023 issues of Drug Safety Update.

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Letters and medicine recalls sent to healthcare professionals in January 2023

National patient safety alert: NIDEK EyeCee One preloaded and EyeCee One Crystal preloaded Intraocular Lenses (IOLs)

On 1 February 2023, we issued a National Patient Safety Alert highlighting action required in response to cases of increased intraocular pressure in patients recently implanted with EyeCee One preloaded and EyeCee One Crystal preloaded intraocular lenses (IOLs), which are manufactured by NIDEK and distributed by Bausch + Lomb U.K. Ltd. Increased intraocular pressure can lead to optic nerve damage and vision loss if left untreated.

A Device Safety Information notification (DSI/2023/001) was issued on 26 January 2023 stating that users should stop using these products immediately and quarantine all preloaded EyeCee One and EyeCee One Crystal preloaded IOLs, pending the results of further investigations. The root cause of the increased intraocular pressure has not been identified and further investigations are ongoing with the manufacturer. A Field Safety Notice (FSN) has been disseminated by Nidek and should be followed.

To protect patient safety, healthcare professionals/teams were asked to contact patients who have received these implants since 1 October 2022 (preferably by telephone) and advise them to have the pressure in their eye tested. Local arrangements for intraocular pressure testing should be agreed and made clear to patients affected. See the alert for more information.

This advice is only relevant to patients who have received preloaded EyeCee One and EyeCee One Crystal preloaded IOLs.

Letters

In January 2023, the following letters were sent or provided to relevant healthcare professionals:

- Januvia 100 mg film-coated tablets (Sitagliptin) - Temporary supply of Januvia 100 mg film- coated tablets in German language packs
- Norditropin (somatropin) NordiFlex® and Norditropin® FlexPro® action needed from prescribers due to supply shortage
- ABRAXANE (paclitaxel albumin) 100mg presentation, 5 mg/ml - powder for dispersion for infusion: UK (GB) Notification of Product Shortage
- Amvuttra 25mg solution for injection in pre-filled syringe (vutrisiran): Interim Supply of German Stock to Enable Early Treatment Prior to Availability of UK (NI) Commercial Stock
- Kevzara▼ 200 mg solution for injection in pre-filled syringe (sarilumab): Interim Supply of German Stock to Mitigate Supply Disruption in Great Britain and Northern Ireland
- Xevudy▼ (sotrovimab) 500 mg concentrate for solution for infusion: Important information for healthcare professionals about the expiry date of all packs

Medicine Recalls and Notifications

In January 2023, recalls and notifications for medicines were issued on:

Class 4 Medicines Defect Information: Albireo AB, Bylvay 1200 micrograms Hard Capsules, EL (23)A/01. Issued 3 January 2023. There is a typographical error with the text on the side panel of the bottle label for a specific batch of Bylvay 1200 micrograms Hard Capsules. The side panel of the bottle label on this batch erroneously reflected the content of the active ingredient as 400 micrograms odevixibat (as sesquihydrate). This should state: “Each capsule contains 1200 micrograms odevixibat (as sesquihydrate)”.

Company led medicines recall: Mawdsley-Brooks & Company Limited, Fluphenazin-neuraxpharm® D 25 & 100 mg/ml Solution for Injection, CLMR(23)A/01. Issued 12 January 2023. Specific batches of product are recalled as a precautionary measure due to validation tests demonstrating the leaching of filter additives that are above the acceptable limit. Remaining stock of the batches listed in the recall should be quarantined and returned to Mawdsleys directly.

Class 2 Medicines Recall: UCB Pharma Ltd, Dioctyl 100 mg Capsules, EL (23)A/02. Issued 18 January 2023. Recall of one batch of Dioctyl 100 mg Capsules as a precautionary measure due to the presence of a foreign capsule being found in a sealed pack. Stop supplying the affected batch, quarantine all remaining stock and return it using your supplier’s approved process.

Class 3 Medicines Recall: Dr Reddy’s Laboratories (UK) Ltd, Lacidipine 4 mg Film-Coated Tablets, EL (23)A/03. Issued 19 January 2023. Recall of two batches of Lacidipine 4 mg Film-Coated Tablets as a precautionary measure due to the presence of an unknown solvent-like odour. Stop supplying the affected batches immediately, quarantine all remaining stock and return it using your supplier’s approved process.

Company led medicines recall: Prulab Pharma Limited, Clopidogrel Oral Solution 75mg in 5ml [unlicensed medicine], CLMR (23)A/02. Issued 25 January 2023. Recall of a batch of Clopidogrel Oral Solution 75mg in 5ml due to a discrepancy with the product labelling that could result in an incorrect volume being administered. Stop supplying the affected batch immediately, quarantine all remaining stock and return using your supplier’s approved process. Pharmacists who have dispensed this unlicensed medicine should review all prescriptions to ensure that the volume of administration corresponds to the clopidogrel dose prescribed. Further instructions are provided in the Direct Health Professional Communication.

Medical Device Safety Information

MHRA Device Safety Information pages have been recently published on the following topics.

Belzer UW Cold Storage Solution and Belzer MPS UW Machine Perfusion Solution manufactured by Carnamedica (UKRP: Bridge to Life): Contamination of fluid; DSI/2023/002.

The manufacturer of these products has identified issues with third-party suppliers, which could result in:

- microbiological contamination
- particulate matter within the solution, and
- leakage of fluid

Belzer UW Cold Storage Solution (CSS) is intended for flushing and cold storage of kidney, liver and pancreas organs at the time of their removal from the organ donor in preparation for storage, transportation and eventual transplantation into a donor recipient.

Belzer UW Machine Perfusion Solution (MPS) is intended for the in-vitro flushing and continuous hypothermic machine perfusion preservation of explanted kidneys.

Actions and advice for transplant unit directors/co-ordinators, healthcare professionals involved in organ retrieval, transfer and transplantation, healthcare professionals and laboratory staff involved in the receipt, use and storage of tissue derived from organs for transplantation, and healthcare professionals and laboratory staff involved in cell isolation work as a function of islet and hepatocyte laboratories are available on the Device Safety Information.

NexGen Knee replacement: affected patients should be offered additional follow up, DSI/2023/003

The National Joint Registry (NJR) has identified that both the NexGen Stemmed Option Tibial Components, when paired with either the Legacy Posterior Stabilized (LPS) Flex Option Femoral or the LPS Flex Gender Solutions Femoral (GSF) Option Femoral, had a higher overall revision rate and a higher revision rate for aseptic tibial loosening compared to the average revision rate of all other total knee replacements in the UK NJR.

The NJR has provided all hospitals with a list of affected patients recorded in the Registry with this combination. For Scotland this will be co-ordinated by health boards. All affected patients should be offered clinical follow up and examination as outlined in the Actions set out in the Devices Safety Information.

For all the latest safety notices from the MHRA on drugs and medical devices, see Alerts and recalls for drugs and medical devices.

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