

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.



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](https://www.nice.org.uk/accreditation).

To subscribe to monthly email alerts of Drug Safety Update see:

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/email-signup>

On page 2, we summarise recent information relating to COVID-19 vaccines published since the July 2021 issue of Drug Safety Update, including information about our review of reports of suspected side effects of menstrual disorders and unexpected vaginal bleeding following COVID-19 vaccination and information about the safety of COVID-19 vaccines in pregnancy.

And on page 4, we include recent letters, recalls and notifications sent to healthcare professionals about medicines. We also link to our announcement related to the reclassification of 2 desogestrel-containing progestogen-only oral contraceptives from prescription-only to pharmacy products for the prevention of pregnancy in women of childbearing age.

COVID-19 vaccines: updates for August 2021

Recent information relating to COVID-19 vaccines that has been published since the July 2021 issue of Drug Safety Update.

Review of reports involving menstrual disorders and unexpected vaginal bleeding

The MHRA is reviewing, with expert advice, reports of suspected side effects of menstrual disorders and unexpected vaginal bleeding following vaccination against COVID-19 in the UK.

The rigorous evaluation completed to date does not support a link between changes to menstrual periods and related symptoms and COVID-19 vaccines. The number of reports of menstrual disorders and vaginal bleeding is low in relation to both the number of people who have received COVID-19 vaccines to date and how common menstrual disorders are generally. Details are included in the [summary of Yellow Card reporting for the COVID-19 vaccines](#).

The menstrual changes reported are mostly transient in nature. There is no evidence to suggest that COVID-19 vaccines will affect fertility and the ability to have children.

It is important that anyone experiencing changes to their periods that are unusual for them, persist over time, or has any new vaginal bleeding after the menopause, following COVID-19 vaccination, should contact their doctor. Anyone presenting with menstrual disorders and/or unexpected vaginal bleeding following COVID-19 vaccination should be treated according to clinical guidelines for these conditions, as usual.

The MHRA continues to closely review reports of suspected side effects of menstrual disorders and unexpected vaginal bleeding. As with any suspected side effects from the COVID-19 vaccines, please continue to report via the Yellow Card scheme. You can also encourage your patients to do the same.

Safety of COVID-19 vaccines in pregnancy

Further information has also been included in the [summary of Yellow Card reporting for the COVID-19 vaccines](#) as the MHRA continues to closely monitor the safety of COVID-19 vaccine exposures in pregnancy, including Yellow Card reports for COVID-19 vaccines used in pregnancy.

The numbers of reports of miscarriage and stillbirth are low in relation to the number of pregnant women who have received COVID-19 vaccines to date and how commonly these events occur in the UK outside of the pandemic. There is no pattern from the reports to suggest that any of the COVID-19 vaccines used in the UK, or any reactions to these vaccines, increase the risk of miscarriage or stillbirth. There is no pattern from the reports to suggest that any of the COVID-19 vaccines used in the UK increase the risk of congenital anomalies or birth complications. Pregnant women have reported similar suspected reactions to the vaccines as people who are not pregnant.

The MHRA will continue to closely monitor safety data for use of the COVID-19 vaccines in pregnancy, including through evaluation of electronic healthcare record data.

Summaries of Yellow Card reporting and other recent MHRA publications

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 will be published regularly to include other safety investigations carried out by the MHRA under the [COVID-19 Vaccine Surveillance Strategy](#).

We have also recently:

- updated the information about the [COVID-19 Vaccine Pfizer/BioNTech](#) for healthcare professionals and recipients to include additional descriptions of anxiety-related reactions, extensive swelling of the vaccinated limb, and facial swelling in people with facial dermatological fillers (see also information in [summary of Yellow Card reporting](#))
- [added a lay summary for Vaxzevria COVID-19 Vaccine \(previously COVID 19 Vaccine AstraZeneca, suspension for injection\)](#)
- published the [Summary of Product Information](#), [Patient Information Leaflet](#) and [Conditions](#) document for the GB Conditional Marketing Authorisation for the [Pfizer/BioNTech vaccine](#)

We have previously provided summaries of the latest COVID-19 information, including in the [May 2021](#), [June 2021](#), and [July 2021](#) issues of Drug Safety Update.

See [guidance on COVID-19 for all our latest information](#), including after publication of this article.

Reporting Yellow Cards

Suspected adverse reactions associated with COVID-19 vaccines should be reported to the MHRA through the MHRA's [Coronavirus Yellow Card reporting site](#) or via the Yellow Card app.

As these products are under additional monitoring this includes all suspected ADRs associated with these vaccines. This will allow quick identification of new safety information.

When reporting please provide as much information as possible, including information about medical history, any concomitant medications, onset, treatment dates, and vaccine product brand name and batch number.

You may be contacted following submission of a Yellow Card report so that we can gather additional relevant information for the assessment of the report. These contributions form an important part of our understanding of suspected adverse events.

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Letters and medicine recalls sent to healthcare professionals in July 2021

Letters

In July 2021, the following letters were sent or provided to relevant healthcare professionals:

- [Xeljanz▼ \(tofacitinib\): Increased risk of major adverse cardiovascular events and malignancies with use of tofacitinib relative to TNF-alpha inhibitors](#)
- [Daptomycin 350 mg and 500 mg powder for solution for injection/infusion \(Daptomycin\): Interim Supply of German Stock to Mitigate Supply Disruption](#)
- [Hemabate Sterile Solution \(Carboprost tromethamine 250 mcg/mL ampoules\): Temporary supply of Hemabate \(Carboprost tromethamine 250mcg/ml\) Injection, USP to mitigate supply disruption](#)

Desogestrel-containing contraceptive pills: reclassification decisions by the MHRA

In July 2021, the MHRA agreed to [reclassify 2 desogestrel-containing progestogen-only oral contraceptives](#) (Hana 75 microgram, [Lovima 75 microgram](#)) from prescription-only (POM) to pharmacy (P) products for the prevention of pregnancy in women of childbearing age. The MHRA's decision to reclassify these desogestrel products follows a safety review by the Commission on Human Medicines (CHM) and public consultation.

See [Hana public assessment report](#) and [Lovima public assessment report](#).

Medicine Recalls and Notifications

In July 2021, recalls and notifications for medicines were issued on:

[Class 2 Medicines Recall: Kyowa Kirin Limited, Xomolix 2.5 mg/ml solution for injection, EL \(21\)A/15](#). Issued 1 July 2021. Two batches of Xomolix (droperidol) 2.5mg/ml solution for injection are being recalled as a precautionary measure due to reports of contamination with glass and cellulose fibres. This particulate contamination could potentially induce local inflammatory responses or lead to embolisation in small capillaries. Stop supplying the batches immediately, quarantine all remaining stock and return to supplier. Where possible, patients who have been recently administered a product from an affected batch should be monitored closely.

[Company led medicines recall: Morphine Syringe 50mg/50ml \(unlicensed medicine\) and Magnesium Sulphate 8mmol/20ml infusion \(unlicensed medicine\)](#). Issued 1 July 2021. A batch of each of the unlicensed medicines morphine syringe 50mg/50ml and magnesium sulphate 8mmol/20ml infusion are being recalled by the company. This is a precautionary recall as batches have been identified to be potentially contaminated. Stop supplying the batch immediately, quarantine all remaining stock and return to supplier.

[Class 4 Medicines Defect Information, Tetralysal 300mg Hard Capsules, \(PL 10590/0019\), EL \(21\)A/16](#). Issued 6 July 2021. Several batches of Tetralysal (lymecycline) 300mg Hard Capsules have been identified to include older versions of the Patient Information Leaflet in the product packs. The affected batches omit safety warnings on precautions, medicine interactions and side effects – full details are available in the medicine notification. There is no risk to product quality as a result of this issue; however, healthcare professionals are advised to exercise caution when dispensing the product and provide an updated Patient Information Leaflet where possible.

[Class 4 Medicines Defect Information, Sevredol 10 mg and 20mg tablets, \(PL 16950/0063, PL 16950/0064\), EL \(21\)A/17](#). Issued 12 July 2021. Several batches of Sevredol (morphine sulfate) 10mg and 20mg tablets have been identified to include older versions of the Patient Information Leaflet. The patient information in the affected batches omits safety warnings on precautions, interactions and possible side effects – full details are available in the medicine notification. There is no risk to product quality as a result of this issue; however, healthcare professionals are advised to exercise caution when dispensing the product and provide an updated Patient Information Leaflet where possible.

[Class 4 Medicines Defect Information, Amoxicillin 500 mg/ 5 ml Powder for oral suspension, \(PL 25298/0248\), EL \(21\)A/18](#). Issued 19 July 2021. Batches of Amoxicillin 500mg/5ml Powder for oral suspension have been identified that state an incorrect amount of the excipient sodium benzoate. There is no risk to product quality as a result of this issue and thus the product is not being recalled. Healthcare professionals are asked to make colleagues in clinics, GP surgeries, and community pharmacies aware for information.

For all of the latest safety notices from the MHRA on drugs and medical devices, including a recent [recall of irbesartan-containing products](#) issued in August 2021, see [Alerts and recalls for drugs and medical devices](#).

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