Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

June 2025

Summary of the latest safety advice for medicines and medical device users

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Valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell▼): updated safety and educational materials to support patient discussion on reproductive risks

Access the full article

Specialisms: *Neurology, Obstetrics, gynaecology and fertility, Psychiatry, General Practice, Pharmacy, Paediatrics and neonatology*

Summary

Updated safety and educational materials are now available to support the implementation of the regulatory measures announced in the November 2023 National Patient Safety Alert and the September 2024 Drug Safety Update. They also include previous updates to product information on the risk of low birth weight in children exposed to valproate during pregnancy.

Key Advice for Healthcare Professionals:

- updated safety and educational materials are now available to support healthcare professionals and patients to implement the existing regulatory requirements
- the updates reflect:
  - precautionary advice on the potential risk of neurodevelopmental disorders in children fathered by men taking valproate around the time of conception
  - a risk of lower weight at birth for the gestational age in children exposed to valproate during pregnancy

- healthcare professionals should review the new materials and integrate them into their clinical practice when referring patients and when prescribing or dispensing valproate

As a reminder

- valproate must not be started in new patients (male or female) younger than 55 years unless two specialists independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply
- valproate must not be prescribed to any woman or girl able to have children unless the conditions of the Pregnancy Prevention Programme (PPP) are followed
- as a precaution, recommend that male patients use effective contraception (condoms, plus contraception used by the female sexual partner) throughout the valproate treatment period and for 3 months after stopping valproate, to allow for one completed sperm cycle not exposed to valproate. For further information see the September 2024 Drug Safety Update
- report suspected adverse reactions associated with valproate on Yellow Card

Key Advice for Healthcare Professionals to Provide to Patients:

- do not stop taking valproate without advice from a specialist. This is because epilepsy or bipolar disorder may worsen without treatment
- women and girls who are able to have children and who are taking valproate must follow the conditions of the Pregnancy Prevention Programme
- as a precaution it is recommended that male patients taking valproate should use effective contraception (condoms, plus contraception used by the female sexual partner) throughout the valproate treatment period and for 3 months after stopping valproate
- if you are on valproate, please attend any offered appointments to discuss your treatment plan and talk to a healthcare professional if you are concerned. If you wish to discuss family planning, please contact a healthcare professional
- consult the Patient Information Leaflet and Patient Guide for men or Patient Guide for women for information about the risks of valproate – also the MHRA information page for information resources

IXCHIQ Chikungunya vaccine: temporary suspension in people aged 65 years or older

Access the full article

Specialisms: *Infection prevention, Infectious disease, Immunology and vaccination*

Summary

The Commission on Human Medicines (CHM) has temporarily restricted use of the IXCHIQ Chikungunya vaccine in people aged 65 years and over following very rare fatal reactions reported globally. This is a precautionary measure while the MHRA conducts a safety review. The IXCHIQ vaccine will be available on the UK market from 18 June 2025.

Key Advice for Healthcare Professionals:

- Chikungunya vaccine (IXCHIQ) is a vaccine to protect against life-threatening Chikungunya virus infection; strict adherence to contraindications and precautions is essential to reduce the risk of very rare but potentially fatal adverse reactions
- following a review of the benefits and risks of the vaccine, CHM has made a recommendation to restrict use of this vaccine in individuals aged 65 years and older, while data is reviewed from global cases
- do not use this vaccine in people aged over 65 years for the period of the suspension the product information for the vaccine will not change during this suspension, but a letter for healthcare professionals will be circulated from the company in addition to this Drug Safety Update, to advise of the restrictions on those aged 65 and above
- XCHIQ vaccine is already contraindicated in all individuals with immunodeficiency or immunosuppression as a result of disease or medical therapy, this includes IgA deficiency
- patients who have received the vaccine should be advised to seek emergency medical attention if they develop signs or symptoms associated with viraemia, including arthralgia, or neurological symptoms including encephalopathy
- all patients who have received the vaccine should receive the manufacturer's patient information leaflet as part of the travel consultation
- further communications will be circulated to inform of the outcome of the review
- report suspected adverse reactions associated with the IXCHIQ vaccine on a Yellow Card

Key Advice for Healthcare Professionals to Provide to Patients:

- the Chikungunya vaccine is given to those who plan to travel abroad to certain regions, where the Chikungunya virus is present. Chikungunya virus is a potentially life-threatening viral infection
- a live attenuated Chikungunya vaccine, IXCHIQ, is coming to the UK market on 18 June 2025, it has not been available on the UK market before this time
- the IXCHIQ vaccine should not be used for people aged 65 years and over until MHRA has completed a full safety review. This is because there have been rare reports of serious side effects in this age group globally
- during your vaccine consultation you will be assessed by a healthcare professional for vaccine suitability, you will not be given this vaccine if you are aged over 65 years old, or if you are immunosuppressed or immunodeficient. Alternative vaccines are available for these groups
- if you have received a Chikungunya vaccine, you should seek urgent medical attention if you start to experience joint pain, fever, stiff neck or confusion

Letters, medicines recalls and device notifications sent to healthcare professionals in June 2025

Direct Healthcare Professional Communications

In June 2025, the following Direct Healthcare Professional Communications were sent or provided to relevant healthcare professionals:

- NovoRapid® PumpCart® 100 units/ml solution for injection in cartridge (insulin aspart): POTENTIAL SUPPLY SHORTAGE

Medicine Recalls and Notifications

In June 2025, recalls and notifications for medicines were issued on:

Class 2 Medicines Recall: Inhixa 12,000IU (120mg)/0.8mL solution for injection, Maxearn Limited, EL(25)A/27. Issued 12 June 2025

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Maxearn Limited have informed the MHRA that the carton used to package two imported batches of Inhixa have been released to the market with a typographical error on one side of the carton.

Class 2 Medicines Recall: Paracetamol 500mg Tablets, Chelonia Healthcare Limited, EL(25)A/25. Issued 9 June 2025

Chelonia Healthcare Limited is recalling specific batches of Paracetamol 500mg Tablets (100 pots) as a precautionary measure due to contamination following a small number of complaints of discoloured tablets within the pots.

Class 4 Medicines defect notification: Dulcolax Adult 5 mg Gastro-resistant Tablets, Opella Healthcare UK, EL(25)A/26. Issued 10 June 2025

Opella Healthcare UK LTD has informed the MHRA that there is an error on the artwork for the outer carton of Dulcolax Adult 5mg GR Tablets (packsize 20 count). The dose instruction incorrectly states for use in 12 years and older. These general sale packs are intended for use only in adult patients (18 years and over).

Class 4 Medicines defect notification: Zentiva Pharma UK Limited, Various Products, EL(25)A/24. Issued 2 June 2025

Zentiva Pharma UK Limited has informed the MHRA of an issue related to batches of various soluble or effervescent tablets.

Medical Device Field Safety Notices

Find recently published Field Safety Notices

Report suspected drug reactions and device incidents on a Yellow Card

Please continue to report suspected adverse drug reactions and device incidents. Your report will help us safeguard public health.

When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates and particularly if a side effect continued or started after treatment was stopped.

Report a medicine

Reporting for medical devices

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Healthcare professionals should report via a Yellow Card to:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store

some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system

Reporting for Patients

Report a medicine or medical device

Patients should report via a Yellow Card to:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store

News Roundup

MHRA releases new guidance on GLP-1 medications, including the requirement for women to use effective contraception

The MHRA has released guidance, aimed at the public, on how to safely use GLP-1 medications (including Ozempic and Wegovy). The guidance advises that individuals of childbearing potential using GLP-1 receptor agonists should use effective contraception during treatment and for a specified period after discontinuation, due to limited safety data in pregnancy. Notably, tirzepatide (Mounjaro) may reduce the absorption of oral contraceptives, particularly in overweight or obese individuals. Therefore, it is recommended to use a non-oral contraceptive method, or add a barrier method, for four weeks after initiating tirzepatide and following each dose escalation. The guidance, which also advises on potential side effects of GLP-1s and the importance of sourcing GLP-1s from a legitimate pharmacy, will be continually updated as any new safety issues arise. Healthcare professionals may wish to direct patients to our guidance as a source of information. For further information on contraception and GLP-1s, healthcare professionals and patients may also wish to consult guidance from The Faculty of Sexual and Reproductive Health (FSRH).

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First major overhaul of medical device regulation comes into force across Great Britain

New Post-Market Surveillance (PMS) regulations have taken effect across Great Britain, requiring medical device manufacturers to proactively monitor the safety and performance of their products once on the market. Read our press release for further information.

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