



# MHRA SAFETY ROUNDUP

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**April 2026**

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

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## Letters, medicines recalls and device notifications sent to healthcare professionals in April 2026

### Direct Healthcare Professional Communications

We received notification that the following Direct Healthcare Professional Communications were sent or provided to relevant healthcare professionals in April 2026:

- [Trumenba 60 µg/dose suspension for injection \(meningococcal group B vaccine \(recombinant, adsorbed\)\) - Provision of packs in foreign language](#)
- [Sodium Chloride 0.9% solution for infusion\(PL 08828/0084\): Interim Supply of USA Labelled Stock to Mitigate Supply Disruption](#)
- [Potential particulates in certain Visipaque \(Iodixanol\) and Omnipaque \(Iohexol\) 100 ml polymer bottles](#)
- [Aurum pre-filled syringes: instructions to ensure box end labels are intact prior to use](#)
- [Enzalutamide Astellas 40mg film-coated tablet: enzalutamide laboratory test interference leading to falsely elevated digoxin plasma levels](#)
- [Methylphenidate hydrochloride: Supply of Meflynate XL 10 mg, 20 mg, 40 mg & 60 mg modified-release hard capsules with blisters strips printed with Spanish labelling. Sent to relevant stakeholders in March 2026.](#)
- [Imatinib Accord 100mg and 400 mg film coated tablets \(imatinib\) - Missing safety information in the Patient Information Leaflet \(PIL\). Sent to relevant stakeholders in March 2026.](#)

### Medicine Recalls and Notifications

In April 2026, recalls and notifications for medicines were issued on:

**[Class 2 Medicines Recall](#): AmaroX Limited, Sertraline 100mg film-coated tablets, EL(26)A/22.** Issued 28 April 2026.

AmaroX Limited is recalling one batch of Sertraline 100 mg film-coated tablets as a precautionary measure due to an error at the manufacturing site.

**[Class 2 Medicines Recall](#): Crescent Pharma Limited, Ramipril 10mg capsules, EL(26)A/19.** Issued 20 April 2026.

Crescent Pharma Limited is recalling one batch of Ramipril 10mg Capsules as a precautionary measure due to a potential error at the manufacturing site.



### **Class 3 Medicines Recall: Omega Pharma Ltd, Napralief 250mg Gastro-Resistant Tablets, EL(26)A/21.** Issued 23 April 2026.

Omega Pharma Ltd is recalling specific batches of Napralief 250mg Gastro-Resistant Tablets due to missing text in Section 2 and Section 3 of the Patient Information Leaflet (PIL) and on the Carton in packs of Napralief 250mg Gastro-resistant tablets.

### **Class 4 Medicines Recall: Doncaster Pharma Limited, Hiprex 1g tablets, EL(26)A/20.** Issued 22 April 2026.

Doncaster Pharma Limited has informed the MHRA of an error related to the Braille embossing on the outer packaging of certain parallel imported batches of Hiprex 1 g tablets (POM).

## 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

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)

### Reporting for medical devices

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 Yellow Card website in accordance with your organisations medical device policies and procedures

### 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

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#### EMA recommends withdrawal of marketing authorisations for levamisole medicines following safety review

In February 2026, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) issued a recommendation that medicines containing levamisole be withdrawn from the EU market following a safety review confirming leucoencephalopathy as a rare but serious side effect. This follows an EU-wide review which concluded that the benefits of these medicines no longer outweigh their risks for the treatment of parasitic infections in adults and children.

Levamisole is a medicine licenced in the EU and indicated for the treatment of mild parasitic infections in adults and children, and is also thought to be a mild immunosuppressant. Levamisole does not hold a current UK marketing authorisation however, levamisole containing medicines are used in the UK off-label in exceptional circumstances to treat children with frequently relapsing or steroid-dependent nephrotic syndrome, to help maintain remission and lower the steroid dosage.

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#### Publication of RSV vaccine factsheet

The MHRA has published a new RSV vaccine factsheet, designed to provide information and guidance for patients, parents and carers about respiratory syncytial virus (RSV), and the vaccines used to protect people at higher risk of serious illness.

The factsheet covers what RSV is, who is eligible for vaccination in the UK, and the safety and effectiveness of RSV vaccines, including information on side effects and vaccination during pregnancy.

This resource is now available for healthcare professionals, patients and the public. For more information, view the full [RSV Vaccine Factsheet – Information for Patients, Parents and Carers](#).

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