Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

March 2025

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

Contents

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Prolonged-release opioids: Removal of indication for relief of post-operative pain

Access the full article here

Specialisms: *Pain management and palliation, Anaesthesia and intensive care*

Summary

The indication for the treatment of post-operative pain has been removed from the licences of all prolonged release opioids. These opioids should not be used post-operatively due to the increased risk of persistent post-operative opioid use (PPOU) and opioid-induced ventilatory impairment (OIVI). It is not recommended to use transdermal patches for the treatment of post-operative pain.

Key Advice for Healthcare Professionals:

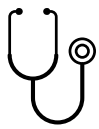
- prolonged-release opioids provide relief from chronic severe pain, however, they should not be used for the treatment of acute pain following surgery
- prolonged-release opioids are associated with an increased risk of PPOU characterised as continued opioid use beyond 90 days following the operation, and an increased risk of OIVI causing serious respiratory depression, sedation, and depression of upper airway muscle tone
- at discharge from hospital:
  - only prescribe and supply a sufficient amount of immediate-release opioids to treat acute post-operative pain to minimise the risk of PPOU, dependence, stock piling of unused opioids and potential for diversion
  - communicate the pain management plan with the primary care practice taking over care in the community and document in patient clinical notes
- patients whose pain is managed with opioids pre-operatively should have their treatment reviewed before and after surgery in line with Consensus Best Practice Guidelines

Key Advice for Healthcare Professionals to Provide to Patients:

- opioids provide relief from moderate to severe pain. Pain following an operation is usually short-lived and therefore should only require short-term treatment
- immediate release opioids are used for the treatment of short-term post-operative pain

Key Advice for Healthcare Professionals to Provide to Patients *continued*:

- if you are taking prolonged release opioids before going into hospital for an operation, talk to your doctor to discuss your pain management and ongoing needs



Suzhou Surgicare disposable Hysteroscopy Sheath– Recall due to withdrawn CE certificate. DSI/2025/001

Access the full article here

Specialisms: *Obstetrics and Gynaecology*

Device Details:

Disposable Hysteroscopy Sheath

Affected Lot Serial Numbers:

All

Manufactured by:

Suzhou Surgicare Medical Technology Ltd

Summary

The MHRA has become aware of Hysteroscopy Sheaths supplied in the UK market with a withdrawn CE certificate. Healthcare professionals and providers should immediately stop use, quarantine, and stop supply of any identified product(s).

Key Advice for Healthcare Professionals:

- Review your inventory and determine if you have any affected devices.
- Immediately stop use, quarantine and stop supply of any identified product(s)
- Return unused stock to the distributor HJ Medical (GyneVision)

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Key Advice for Healthcare Professionals *continued*:

- Providers should ensure all relevant members of staff receive this safety information and that they understand the problem and actions to be taken.
- Report any suspected or actual adverse incidents involving these devices. There are specific reporting arrangements for healthcare professionals to follow in each region. Please see the reporting section of this bulletin for further information.

Key Advice for Healthcare Professionals to Provide to Patients:

- There is no advice for healthcare professionals to provide to patients regarding this DSI

Letters and medicine recalls sent to healthcare professionals in February and March 2025

Direct Healthcare Professional Communications

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

- MOVICOL range products: update to the product names and/or reconstituted solution shelf-life
- Trulicity® (dulaglutide) 0.75 mg and 1.5 mg solution for injection in pre-filled pen, Batch Specific Variation, Batch D761603A, D764386A, D761462A
- Magnesium Kora Healthcare 4mmol (97 mg) tablets (Magnesium citrate nonahydrate): Supply of Magmedi 97mg tablets
- Emblaveo® (aztreonam/avibactam) 1.5 g/0.5 g powder for concentrate for solution for infusion: potential for cracked or broken vials (PLGB 00057/1721)
- COMIRNATY® KP.2, 30 micrograms/dose dispersion for injection in pre-filled syringe (glass): supply in EU approved artwork (Cartons and syringe labels)
- Lytgobi▼ 4 mg film-coated tablets (futibatinib): Interim Supply of Spain Stock to Mitigate Supply Disruption
- Concerta XL 27 mg prolonged-release tablets (methylphenidate hydrochloride): Interim Supply of Finnish and Norwegian Stock to Mitigate Supply Disruption
- Supply termination of Promixin 1MIU Powder for Nebuliser Solution (colistimethate sodium), I-neb AAD device and I-neb consumables - advice to transition patients

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- Scopoderm (hyoscine) change of manufacturing site
- DISCONTINUATION OF: NovoRapid® FlexTouch® 100 units/ml solution for injection in 3 ml pre-filled pen (insulin aspart) and Insulatard® Penfill® 100 units/ml suspension for injection in cartridge (isophane insulin human)

Medicine Recalls and Notifications

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

Class 2 Medicines Recall: Nitrofurantoin CNX Therapeutics 100 mg Prolonged-Release capsules, EL(25)A/05. Issued 5 February 2025.

CNX Therapeutics is recalling the batches listed in this notification as a precautionary measure due to a small number of packs that contain an additional tablet of Nitrofurantoin. The registered product is a capsule containing powder and two yellow tablets.

Class 2 Medicines Recall: Sun Pharmaceutical Industries Europe B.V., Pemetrexed 1000MG/100ML (10mg/ml) & 800MG/100ML (8mg/ml) Infusion bag, EL(25)A/09. Issued 4 March 2025.

Sun Pharmaceutical Industries Europe B.V. is recalling those product batches listed in this notification as a precautionary measure due to out of specification results reported for the Particulate Matter Test (PMT) during stability testing.

Class 2 Medicines Recall: Boots Paracetamol 500 mg tablets (16s), EL(25)A/10. Issued 4 March 2025.

Aspar Pharmaceuticals Limited have informed the MHRA of an error related to a batch of Boots Paracetamol 500 mg tablets (16s). The foil blister inside the carton incorrectly states ‘Aspirin 300 mg Dispersible Tablets’. The tablets are confirmed to be Paracetamol 500 mg tablets.

Class 3 Medicines Recall: Glucophage SR 500 mg, 750mg and 1000mg Prolonged-release Tablets, EL(25)A/07. Issued 20 February 2025.

All batches of the named products are being recalled by the Marketing Authorisation Holder in Italy and subsequent UK parallel distributor companies as a precautionary measure due to the product being manufactured with the incorrect grade of an excipient.

Class 3 Medicines Recall: Azacitidine 100 mg/vial and 150 mg/vial Powder for Suspension for Injection, EL(25)A/08. Issued 3 March 2025.

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Accord Healthcare Limited is recalling certain batches of Azacitidine Powder for Suspension for Injection 100 mg/vial and 150 mg/vial as precautionary measure due to out of specification results for Azacitidine related compound C impurity during stability testing.

Class 4 Medicines Notification: **Lansoprazole Gastro-resistant Hard Capsules 15mg, EL(25)A/06.** Issued 11 February 2025.

Teva UK Limited is reporting a minor typographical error on the carton for Lansoprazole Gastro-Resistant Hard Capsules 15mg. There are two instances where the dosage form is stated as “tablets” where it should state “gastro-resistant capsule, hard”.

UPDATE: Class 4 Medicines Defect Notification: Azithromycin 250 mg Capsules, EL(25)A/11. Updated 12 March.

Jubilant Pharmaceuticals NV has informed the MHRA that the Patient information leaflet (PIL) in the cartons for the batches listed is outdated.

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 Northern Ireland Adverse Incident Centre and their local incident recording system

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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

Valproate Pregnancy Prevention Programme: COVID-19 guidelines

The Valproate COVID-19 guidance, which provided temporary advice for management of the Pregnancy Prevention Programme during the coronavirus pandemic was published in May 2020. This guidance has now been retired.

The Summary of Product Characteristics for valproate containing products outlines the conditions of the Pregnancy Prevention Programme but does not specify how a review with a patient should be held. This includes whether reviews should be held face to face or remotely. If remote consultations are considered appropriate these should be conducted in line with relevant local clinical guidance.

Potency labelling of topical steroids

Following calls from the National Eczema Society that was supported by many organisations including the British Association of Dermatologist (1) topical steroids will be labelled to inform users of their potency. Potency will be labelled in line with the ATC code, included in the Summary of Product Characteristics, which is based on the corticosteroid component, irrespective of the formulation and strength. For a small number of products this raises some discrepancies (2) with the previous BNF potencies. Prescribers should give clear advice to patients using these products. Please refer to the Drug Safety Update article on Topical steroids: introduction of new labelling and a reminder of the possibility of severe side effects, including Topical Steroid Withdrawal Reactions - GOV.UK

MHRA Guidance on Safety Communications

MHRA has published guidance and an infographic on GOV.UK to help our readers understand the different types of safety communications (for both medicines and medical devices) that we publish and how to locate and subscribe to them. This can be found here: Safety communications concerning medicines, medical devices and other healthcare products

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