KING'S HEALTH PARTNERS

An Academic Health Sciences Centre for London

Pioneering better health for all

Medicines Safety Bulletin

July 2025

Prolonged release opioids are not indicated for acute pain management

The MHRA has changed the Product Licence of all prolonged release opioid products. These formulations are no longer indicated for acute post-operative pain because of the increased risk of long-term use and a greater risk of respiratory impairment. Prolonged release opioids are not indicated for any type of acute pain management. Persistent post-operative opioid use (PPOU) is defined as continuous opioid use beyond 90 days post-surgery. Prolonged release opioids are linked to PPOU which may lead to sedation, and opioid-induced ventilatory impairment, causing serious respiratory depression.

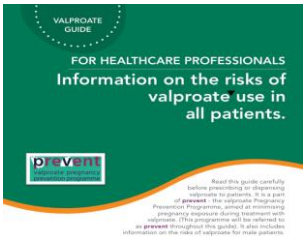
Pain following surgery is usually short-lived, lasting between 5 – 7 days, and should only require short-term pain management. This pain is best treated with immediate release opioids. Immediate release opioids have a faster onset and shorter duration of action, allowing greater dosing flexibility and titration of dosing based on changing pain levels. Immediate release opioids are also associated with a lower risk of overdose in opioid-naïve patients. Morphine modified release (MR) and oxycodone modified release (MR) are the most commonly used prolonged release opioids across KHP Trusts. Both morphine and oxycodone are available in immediate release formulations – these may be used for acute pain. Patients who are on prolonged release opioids prior to surgery, for example for chronic pain, require specialist management – liaise with anaesthetics and pain team for guidance.

Advice for staff:

- Only use immediate release opioids for post-operative pain.
- Involve patients in managing their pain before and after surgery.
    - Reassure patients pain will be short-term and should improve over days
    - Explain how to use non-medication techniques, 'simple analgesics' and immediate release pain relief
    - Emphasise the fact that stopping opioid pain relief is important to avoid addiction and other problems
- At discharge from hospital:
    - Prescribe and supply only a sufficient amount of immediate release opioids to treat acute post-operative pain
    - Explain how to use pain relief effectively, and how to reduce doses and then stop
    - Ensure patients know how to safely store opioids and to dispose of any surplus
    - Ensure patients understand the risks of driving, operating machinery and taking other sedatives e.g. alcohol
- Document and communicate to the patient's primary care practice using the discharge summary:
    - The pain management and weaning plan
    - The opioid dose, amount supplied and intended duration of use

Please bring this newsletter to the attention of all staff

Medicines with reproductive risks: MHRA valproate safety updates



Sodium valproate▼ valproic acid▼ and valproate semisodium▼ are prescribed for epilepsy or bipolar disorder. Valproate has a high teratogenic potential and use in pregnancy leads to a high risk of developing neurodevelopmental disorders (30–40% risk) and congenital malformations (11%). A possible association also exists for male patients taking valproate around the time of conception and an increased risk of neurodevelopmental disorders in their children.

Key messages:

- Valproate **must not be started** in new patients **(female or male) younger than 55 years** unless two specialists independently 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 are followed.
- There is potential risk in **male patients** treated with valproate and for 3 months after stopping therapy. Remind male patients to use effective contraception (condoms, including contraception used by the female partner).

Refer to local Trust guidance for information on valproate prescribing pathways.

Advice for staff:

- Consider reproductive risk when prescribing, dispensing or administering **all medicines,** not just valproate.
- Use a shared decision-making approach to educate patients on the risks involved so that they can make informed choices about their treatment
- Resources on medications with reproductive risk:
  - Valproate:
    - Healthcare professionals Guide
    - Patient guide for men
    - Patient guide for women
    - Patient card
  - Home - electronic medicines compendium (emc)
  - Bumps - Best use of medicines in pregnancy

Connector compatibility changes for Aurum pre-filled syringes

In 2023, the MHRA declared that Aurum pre-filled syringes, containing emergency medications, may be incompatible with some needle-free connectors (NFC). This incompatibility can cause blockage and damage to the NFC leading to failure to administer the medicine. Hospitals are required to review compatibility of their NFC with Aurum syringes connector. The manufacturer is now introducing a new 10mL CONNECT barrel for adrenaline, amiodarone and calcium chloride which is compatible with a wider range of connectors. The old pre-filled syringes may be available until March 2028.

Local medical device teams and safety teams are managing the risk on behalf of each Trust. More information is available here.

Contacts:

GSTT: gstt.medicinessafetyofficerteam@nhs.net; alice.oborne@nhs.net
KCH: Bianca.Levkovich@nhs.net; kch-tr.mso@nhs.net
SLaM: Siobhan.Gee@slam.nhs.uk
KHP Pharmaceutical Sciences: David.Taylor@slam.nhs.uk

Please bring this newsletter to the attention of all staff