Medicines Safety Newsletter

NHS North East London

Issue 6 – October 2024

Promoting Safe Use of Medicines Across Primary Care

Welcome to the sixth issue of our Medicines Safety Newsletter from the North East London (NEL) Medicines Safety and Quality Group. Our aim is to highlight medicines safety concerns and updates raised nationally and locally to support and promote safer use of medicines across North East London

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Latest News

I. #MedSafetyWeek 4 – 10 November

#MedSafetyWeek is an international campaign that takes place annually in November to raise awareness of adverse drug reactions (ADRs) and national reporting systems. The Medicines and Healthcare products Regulatory Agency (MHRA) relies on ADR reporting systems to ensure medicines use is safe. This year will be the ninth annual #MedSafetyWeek campaign and it will take place on 4 to 10 November 2024.The theme will be '**the importance of using medicines in the right way to prevent side effects, and to report side effects when they do occur**'.

In the UK, the focus is on the importance of reporting suspected adverse reactions to medicines and vaccines, but also encouraging the reporting of suspected problems with medical devices or other healthcare products to the Yellow Card scheme. Healthcare professionals are being asked to support the campaign and talk to their

patients and colleagues about side effects and how they can report suspected problems to the MHRA Yellow Card scheme. Click here for further details.

II. EXTENDED RESTRICTIONS ON USE OF GONADOTROPHIN-RELEASING HORMONE (GNRH) ANALOGUES IN GENDER INCONGRUENCE OR GENDER DYSPHORIA IN CHILDREN AND YOUNG PEOPLE UNDER 18 YEARS OF AGE

Since 3 June 2024, the government placed temporary emergency restrictions on the use of gonadotrophin releasing hormone (GnRH) analogues used to suppress puberty as part of treatment for gender incongruence or gender dysphoria in children and young people under 18 years of age. GnRH analogues include medicines that consist of, or contain, buserelin, gonadorelin, goserelin, leuprorelin acetate, nafarelin or triptorelin. The restrictions currently will expire at the end of 26 November 2024 across the UK. For further information please see the NHS England notification here.

It remains a criminal offence for a doctor, pharmacist or any other individual in England to sell or supply GnRH analogues to patients under 18 years of age – except in the following circumstances:

- The child or young person is prescribed these medicines on an NHS prescription from specialist services e.g. NHS Children and Young People's Gender Service.
- The patient is under 18 years old and the prescription is for a purpose other than the treatment of gender incongruence or gender dysphoria,
- The patient is under 18 years old and has started treatment with these medicines, and for these purposes they will be treated as having started treatment if they have been issued with a prescription for these medicines since 3 December 2023, even if they have not yet started taking the medicines.
- The child or young person is prescribed these medicines on a private prescription from a UK prescriber that fulfils the following criteria:
    - The prescription was dated prior to 3 June 2024
    - It is a repeat prescription but only when the initial prescription was written in the 6 months prior to 3 June 2024

Actions for Practices:

- Do NOT start new initiations of GnRH analogue prescriptions to supress puberty for gender incongruence or gender dysphoria in children and young people under 18 years of age in primary care.
- Annotate GnRH analogue prescriptions for patients continuing pre-existing treatment for gender dysphoria or gender incongruence or for conditions not including gender dysphoria or gender incongruence as "SLS" (Selected List Scheme).

III. NEW SAFETY MEASURES – VALPROATE USE IN MEN: AS A PRECAUTION, MEN AND THEIR PARTNERS SHOULD USE EFFECTIVE CONTRACEPTION

Valproate (sodium valproate, valproic acid and valproate semisodium) is primarily used in epilepsy and bipolar disorder. It is also used outside of the license ('off label') to treat other conditions. Valproate is subject to a national patient safety alert due to significant risk of harm to babies upon exposure during pregnancy. New evidence has shown a possible association between valproate use in men at conception with increased risk of neurodevelopmental disorders in children.

Safe Use of Valproate in NEL:

The North East London (NEL) Teratogenic Medicines Safety Improvement group will provide oversight to support providers (primary and secondary care, mental health trusts) with the implementation of these new safety

measures. OptimiseRx messages have been updated to reflect this alert. Please review prescriptions and patients in line with the messages.

Action for Practices:

- Initiate an EMIS (or SystmOne) search to identify male patients prescribed valproate.
- Inform male patients (of any age) who may father children while they are taking valproate or in the 3 months after stopping valproate, there is a potential small increased risk of the child being diagnosed with a mental or movement related developmental disorder (neurodevelopmental disorder) at initiation of valproate or at their next regular treatment review.
- 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 to pass after stopping valproate.
- recommend they allow 3 months to pass (e.g. one complete sperm cycle with no valproate exposure) before trying to father a child
- at the next regular treatment review, discuss with men on oral valproate treatment whether they are planning a family in the next year and if they are, refer to a specialist to discuss alternative treatment options.
- advise male patients, **do not stop taking valproate** unless you are advised to do so by a healthcare professional.
- if a female patient reports they are pregnant or planning a pregnancy with a man on valproate (including those undergoing IVF), refer for prenatal counselling.
- advise men not to donate sperm during valproate treatment and for 3 months after stopping valproate.
- Further information and advice will be added to the valproate patient guide; in the meantime, see MHRA's Advice for male patients on valproate to use contraception and visual risk communication diagram to be used by a healthcare professional when counselling on the risks.
- For further details about the MHRA Drug Safety Update visit valproate use in men as a precaution: Men and their partners should use effective contraception
- Please continue to report suspected adverse drug reactions to the Yellow Card scheme.

Central Alerting System (CAS) alerts

IV. KAY-CEE-L® (POTASSIUM CHLORIDE 5MMOL/5ML) SYRUP

Kay-Cee-L® (potassium chloride 5mmol/5ml) syrup will be out of stock from late September 2024. The resupply date is to be confirmed. See the full details of the alert, including actions required here (click on the attachment in the alert). The supply disruption is caused by an amendment to the manufacturing process, requiring re-formulation, and revalidation of the product.

Alternative options:

- Sando-K® (potassium bicarbonate 400mg and potassium chloride 600mg) effervescent tablets remain available and can support a full increase in demand. One effervescent tablet contains 12mmol potassium.
- Unlicensed potassium chloride oral solutions manufactured within the UK are available via Specials manufacturers.
- Remaining supplies of Kay-Cee-L® syrup should be prioritised for patients requiring doses of less than 12mmol of potassium and where other preparations are not suitable.

Care is needed to ensure selection of the most appropriate oral potassium supplement and delivery of the correct dosage.

V. SHORTAGE OF PANCREATIC ENZYME REPLACEMENT THERAPY (PERT)

There are limited supplies of pancreatic enzyme replacement therapies (PERT).

- Creon® 10,000 and 25,000 capsules are in limited supply until 2026.
- Nutrizym® 22 capsules are out of stock until mid-August 2024. (This product is available now).
- Pancrex V® capsules and powder remain available but are unable to support an increase in demand.

The supply disruption of Creon® capsules is due to limited availability of active pharmaceutical ingredients and manufacturing constraints to produce the volumes required to meet demand.
The supply disruption for Nutrizym® 22 capsules has been caused by a manufacturing issue and increased demand because of the Creon® supply issue.
PERT is indicated for the treatment of pancreatic exocrine insufficiency such as in cystic fibrosis, pancreatic cancer, and pancreatitis. There is no clinical alternative to PERT.
Unlicensed imports of Creon® capsules and alternative brands of PERT may be sourced, lead times vary.
See the full details of the alert, including actions required here (click on the attachment in the alert).

Learning from Patient Safety Events (LFPSE)

Using patient safety events data to keep patients' safe makes the NHS safer for our patients.
Practice staff should use the Learn from Patient Safety Events (LFPSE) system for any events where:

- a patient was harmed or could have been harmed.
- there has been a poor outcome, but it is not yet clear whether an incident contributed or not.
- risks to patient safety in the future have been identified.
- safe and effective care has been delivered that could be learned from to improve patient safety.

The LFPSE system allows for positive local responses to patient safety events. This supports effective management, mitigation and learning activities. Events recorded in LFPSE can be used for significant event analysis. They can also be used for continuing professional development and reflective practice. Further information can be found in the CQC GP mythbuster on recording patient safety events with the Learn from patient safety events (LFPSE) service

A primary care-specific LFPSE information site that explains how to log onto the system and record an event, with user guides is available. While we appreciate that general practice is incredibly busy, recording safety issues on LFPSE offers multiple benefits to practices in addition to improving medicines safety.

MHRA Latest Drug Safety Updates

July - October 2024

MHRA Latest Safety Alert

- Valproate use in men: as a precaution, men and their partners should use effective contraception

Letters sent to relevant healthcare professionals

- Drug safety updates, letters and medicine recalls sent to healthcare professionals in August 2024
- Yellow Card Biobank: call to contribute to study of genetic links to side effects
- Drug safety updates, letters and medicine recalls sent to healthcare professionals in July 2024

Medicine Recalls and Notifications

All medicines recalls and notifications for the period of July to October 2024, can be accessed here: Alerts, recalls and safety information: drugs and medical devices. Please note:

- Class 2 Medicines Recall: Pfizer Limited, Oxbryta 500mg Tablets (voxelotor), EL(24)A/44 - GOV.UK
- Class 2 Medicines Recall: Bristol Laboratories Ltd, Phenobarbital Bristol Labs 15mg Tablets, EL(24)A/50

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Additional Medicines Safety Resources

- **MHRA** - for all MHRA updates on alerts, recalls and safety information on drugs and medical devices, click here
- **Specialist Pharmacy Service (SPS)** – for Medication Safety Updates collating the latest medication safety communications and publications to inform, support and inspire medication safety improvements. For updates, click here July August September 2024
- **SPS - Medicine Supply Shortages and discontinuations –** for updates on medicines shortages and guidance, access SPS medicines tools (register here with SPS free-of-charge to access).
- **PrescQIPP** - for medicines safety tools and resources, click here
- Report suspected adverse effects with medicines, devices, or COVID-19 vaccines via the Yellow Card scheme or Coronavirus Yellow Card reporting site
- **Learning from Patient Safety Events (LFPSE)** – for reporting patient safety incidents and misses via the LFPSE
- **Reporting of Controlled Drug incidents in primary care –** for reporting incidents or concerns related to controlled drugs (including loss or theft) via the online Controlled Drugs Reporting website

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