

Medicines Optimisation Newsletter

[December 2023] (Issue No. 53)



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Licensing of anastrozole for primary prevention of breast cancer

NHS England has issued circular SSC2582 - *Licensing of anastrozole for primary prevention of breast cancer* (see attached below). We would like to draw your attention to both the letter and the updated SPC for anastrozole 1mg tablets.

Key Points:

The [NICE guideline on familial breast cancer](#) has recommended anastrozole off-label since 2017. The NICE guideline has been updated to reflect that anastrozole is now licensed for prevention.

The NICE update is supported by the position of Anastrozole across the K+M formularies as 'specialist initiation' meaning that prescribing can be continued in primary care following specialist initiation.

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Information for patients has been produced by [NICE](#) and, separately, [Breast Cancer Now](#). The NICE [patient decision aids](#) have been updated to include the most recent trial data on anastrozole for prevention.

NHS England (formerly Health Education England) has produced an e-learning for healthcare module on [breast cancer primary prevention education](#). This will be updated to reflect the licence variation for anastrozole.

- [issue-53-licensing-of-anastrozole-for-primary-prevention-of-breast-ca.pdf \(medwayswaleformulary.co.uk\)](#)
- [Licensing of anastrozole for primary prevention of breast cancer \(medwayswaleformulary.co.uk\)](#)

[Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients](#)

The National Patient Safety Agency (NatPSA) issued Alert [Natpsa_2023_013_MHRA.pdf](#) on November 28th 2023 concerning the known significant risk of serious harm to a baby after exposure to valproate in pregnancy. The alert recommends that a new or existing group is set up to co-ordinate the implementation of the new regulatory measures for oversight of valproate prescribing to new and existing patients.

The regulatory change in January 2024, for oral valproate medicines, means that:

- A. 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.
- B. At their next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgement Form, which will include the need for a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes.

The actions required to implement these measures are to begin as soon as possible and be completed by 31 January 2024

[Formulary and Guidance](#)

New Dementia Guidelines in Kent and Medway

The dementia medication prescribing guidance has been updated to reflect the current NICE [NG97] guidance. It outlines the responsibilities of specialist prescribers when initiating people on cognitive enhancing medication ensuring they are on established on a stable dose of medication for a minimum of one-month supply before transferring responsibility to primary care. For people with an established diagnosis of Alzheimer's disease who are already taking an Acetylcholinesterase inhibitor and additional therapy is required, GPs may start treatment with memantine if confident to do so on the advice of a specialist/clinician.

The guidance also covers treatment choices, prescribing guidance as well as how Primary Care colleagues seeking medication advice and guidance can contact the Consultant Psychiatrist and the community mental health team for support.

Please find the approved Kent and Medway guideline embedded below, which can now be used and shared.

The guidelines will be uploaded to all formulary websites in due course.

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Along with the guidelines being approved and updated, the formulary websites will also be updated in due course to reflect this, for now please use the products listed within the guidelines for formulary choices.

[dementia-medication-prescribing-guidance.pdf \(medwayswaleformulary.co.uk\)](#)

Kent and Medway List of New Approved Guidelines

Please find attached a list of New Approved Guidelines from the Integrated Medicines Optimisation Committee (IMOC) October 2023.

[issue-53-kent-and-medway-list-of-new-approved-guidelines.pdf \(medwayswaleformulary.co.uk\)](#)

Learning and Development

NIHR Evidence Webinar 30th January 2024: How can we reduce antibiotic use in primary care?

NIHR is [hosting an webinar on 30th January 2024, at 13:00](#). This webinar will cover NIHR research that could help reduce antibiotic prescribing in primary care. Speakers will present actionable evidence on antibiotic stewardship, and safe and effective prescribing. Presentations will be followed by a Q&A session, giving you a unique opportunity to quiz the researchers on how this research could be implemented at your organisation and reflect on potential barriers and facilitators. The webinar will cover; making decisions about who is in most need of antibiotics, if antibiotics are needed for children with chest infections, and how digital tools can help reduce antibiotic prescribing.

National Updates

National Patient Safety Alerts

The MHRA Central Alerting System alerts can be accessed at <https://www.cas.mhra.gov.uk/Home.aspx>

[Potential for inappropriate dosing of insulin when switching insulin degludec \(Tresiba\) products](#)

Tresiba (insulin degludec) NPSA & High Strength Insulin

The Kent and Medway Medicines Optimisation Team would like to remind colleagues about the shortage of Tresiba (insulin degludec) FlexTouch 100 units/ml solution for injection pre-filled pens. A tier 2 medicines supply notification (MSN) was issued on 24th of May 2023 and cascaded to practices on 25th May 2023. The contents of the MSN and how to manage this supply issue can be viewed on the [Medicines Supply Tool](#). The Tool also details any updates and changes to re-supply dates. To access the Tool you will be required to register (free) with the [SPS website](#). To note the supply issues are expected to last until 31st of December 2024.

A National Patient Safety Alert (NPSA), [Potential for inappropriate dosing of insulin when switching insulin degludec \(Tresiba\) products](#), has now been issued on 8th of December 2023.

- The Medication Safety Officer (MSO) network has highlighted that in response to this shortage, some patients may have been switched to Tresiba® (insulin degludec) FlexTouch® 200units/ml solution for

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injection 3ml pre-filled pens. Tresiba® FlexTouch® pen delivery devices dial up in unit increments rather than volume.

- However, a small number of patients have been incorrectly advised to administer half the number of units. MSOs have highlighted five reports of patients being incorrectly advised to reduce the number of units of insulin to be administered. These reports suggest that errors have occurred at the prescribing, dispensing and administration stages of the medicine journey. One case described a patient requiring treatment in hospital for diabetic ketoacidosis because of a reduced insulin dose.
- Please see the link to the NPSA above which provides further background and clinical information and actions for providers by the 22nd of December 2023.

The Kent and Medway Medicines Optimisation Team would also like to remind colleagues about the MHRA drug safety update [High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error](#).

It is important that healthcare professionals understand the strengths of available insulin products, the differences between them and how to use them correctly; to minimise the risk of medication errors, such as the wrong insulin dose being administered.

High strength insulins have concentrations greater than 100 units/ml. Examples of insulin products which have high strength preparations available include, for example:

- Toujeo (insulin glargine 300 units/ml).
- Humalog (insulin lispro 200 units/ml).
- Tresiba (insulin degludec 200 units/ml).

The MHRA alert includes information on:

- Dose conversion when switching between standard and high strength insulin products.
- The 'dose step', which is a term to define how patients dial up the required drug dose on the prefilled pen.

Please also see the MHRA Drug Safety Update on [Insulin Degludec \(Tresiba\): available in additional higher strength](#).

General prescribing advice for high strength insulins:

- Consult the individual Summary of Product Characteristics (SPC) and educational material before prescribing.
- Prescribe insulin by brand name. Include the strength (units per ml) and presentation (e.g., cartridge or disposable pen). Write the insulin dose in units ("units" to be spelled out and in lower case), timing and frequency.
- The pen device shows the number of units of insulin to be injected irrespective of strength; therefore, the insulin dose may stay the same.
- Seek advice on blood glucose monitoring and dose adjustment from the Diabetes Specialist Team if unsure.
- Check the patient has:
 - Received appropriate training on the correct use of the product and understands the dose required and use of the pen device.
 - Read and understands the patient leaflet and any patient education material.

[Potential contamination of some carbomer-containing lubricating eye products with Burkholderia cenocepacia - measures to reduce patient risk](#)

A [Field Safety Notice \(FSN\)](#) issued on 24 November 2023 recalled batches of three carbomer-containing lubricating eye gels (Aacarb, Aacomer and Puroptics). The Medicines and Healthcare products Regulatory Agency (MHRA) issued accompanying [Device Safety Information \(DSI\)](#) with advice to health professionals, patients and customers.

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UKHSA has issued recommendations on the use of carbomer-containing lubricating eye products following potential contamination of some products with *Burkholderia cenocepacia*.

B. cenocepacia is an opportunistic pathogen which rarely causes infection in healthy individuals but can cause severe infections with significant health consequences in some groups.

As a precautionary measure, while further testing is conducted, avoid use of all carbomer-containing lubricating eye products for patients in the following groups:

- individuals with cystic fibrosis
- patients being cared for in critical care settings (e.g., adult, paediatric and neonatal ICU)
- severely immunocompromised
- patients awaiting lung transplantation.
- Clinicians may wish to extend these measures outside of these categories to individuals who they consider to be very high risk of invasive infection based on their clinical judgement.

Other non-carbomer-containing products are available [here](#)

Please see [National Patient Safety Alert](#) for full details.

MHRA Drug Safety Update

The latest MHRA Drug Safety Updates can be accessed at [Drug Safety Update - GOV.UK \(www.gov.uk\)](#). This includes links to alerts, recalls and safety information and to the monthly Drug Safety Update PDF newsletter.

The November 2023 Drug Safety Update includes:

[Ozempic ▼ \(semaglutide\) and Saxenda \(liraglutide\): vigilance required due to potentially harmful falsified products - GOV.UK \(www.gov.uk\)](#)

Be aware that falsified Ozempic and Saxenda products have been found in the UK, including falsified pens containing insulin, which may lead to patient harm. Please see the MHRA Drug Safety Update for further advice.

[Nirmatrelvir, ritonavir \(Paxlovid ▼\): be alert to the risk of drug interactions with ritonavir - GOV.UK \(www.gov.uk\)](#)

There is a risk of harmful drug interactions with the ritonavir component of the COVID-19 treatment Paxlovid ▼ due to its inhibition of the enzyme CYP3A, which metabolises many commonly used drugs. Prescribers should obtain a detailed patient history of current medications before prescribing Paxlovid, checking the Paxlovid product information for known and potential drug interactions.

[E-cigarette use or vaping: reminder to remain vigilant for suspected adverse reactions and safety concerns and report them to the Yellow Card scheme - GOV.UK \(www.gov.uk\)](#)

[Letters and medicine recalls sent to healthcare professionals in October 2023 - GOV.UK \(www.gov.uk\)](#)

Please follow the link in the titles above for more information and resources.

NICE News – December 2023

Please find the latest NICE news for December 2023 attached.

[recent-nice-publications-dec-23.pdf \(medwayswaleformulary.co.uk\)](#)

Shortages

Medicine Supply Notification: Bumetanide 1mg and 5mg tablets

The Department of Health and Social Care (DHSC) has issued a medicine supply notification (MSN/2023/094) for bumetanide 1mg and 5mg tablets.

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- Bumetanide 1mg tablets are out of stock until January 2024
- Bumetanide 5mg tablets are out of stock until early March 2024
- Bumetanide 1mg/5ml SF oral solution remains available but is unable to support increased demand
- Furosemide 20mg and 40mg tablets remain available and can support increased demand
- Where these are not suitable, unlicensed supplies of bumetanide 1mg and 5mg tablets may be sourced, lead times vary (refer to the [Community Pharmacy England website](#) for information on sourcing unlicensed products).

Actions for primary and secondary care

No new patients should be initiated on bumetanide 1mg and 5mg tablets until the supply issue has resolved.

Where existing patients have insufficient supplies of bumetanide tablets to last until the re-supply date, clinicians should:

- Review patients to determine if this is still the most suitable therapy
- Reserve any remaining stock of bumetanide 1mg tablets for patients using this strength who are unsuitable for a switch to furosemide
- Consider prescribing furosemide tablets which are able to support the market during this time, ensuring that the patient is not intolerant to any of the excipients and is counselled on the appropriate dose to take
- Only consider prescribing unlicensed products where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary

If the above options are not considered appropriate or symptoms are not controlled on furosemide, advice should be sought from specialists on management options.

For more information see supporting information from SPS [Shortage of Bumetanide 1mg and 5mg tablets – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)

[Medicine Supply Notification: Bumetanide 1mg and 5mg tablets - Community Pharmacy England \(cpe.org.uk\)](#)

ADHD medicines supply disruption update

The Department of Health and Social Care (DHSC) issued a [National Patient Safety Alert](#) on supply disruptions affecting various strengths of the following medications for the treatment of attention deficit hyperactivity disorder (ADHD) in September.

Please find further information attached below and updated re-supply dates. Not all drugs and strengths are impacted, therefore the individual patient's medication and quantity should be reviewed before signposting.

A gentle reminder that community pharmacies will only be able to dispense what is written on the prescription, therefore new prescriptions will be needed for changes to the drug, dose or strength. This is a legal requirement, please bear this in mind. A phone call to local pharmacies to understand stock levels prior to prescribing is recommended.

We appreciate that the supply disruption will cause anxiety for patients and their families. NHS Kent and Medway has set up a non-clinical helpline for patients who would like more information on the supply

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disruption (01634 335095 option 3 then option 3, ADHD medicine shortages). This may help you to support the messaging for patients.

[issue-53-adhd-update-15-dec-23.pdf \(medwayswaleformulary.co.uk\)](https://www.medwayswaleformulary.co.uk/issue-53-adhd-update-15-dec-23.pdf)

Shortages Summary

Please find the medicines shortages update (up until 13th December 2023) attached. Practices are encouraged to register for access to the SPS website <https://www.sps.nhs.uk/> and access the full medicines supply tool directly in real time.

[shortages-summary-issue-53-dec-23.pdf \(medwayswaleformulary.co.uk\)](https://www.medwayswaleformulary.co.uk/shortages-summary-issue-53-dec-23.pdf)

From everyone in the Medicines Optimisation Team at NHS Kent and Medway we wish you a very Merry Christmas and a wonderful New Year.



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