Think Medicines!

NHS
Cambridgeshire and Peterborough
Clinical Commissioning Group

Issue 30
January 2020

Safety

MHRA DRUG SAFETY UPDATES - WINTER 2019

HORMONE REPLACEMENT THERAPY

Further information on the known increased risk of breast cancer with all types of HRT, except vaginal estrogens and its persistence after stopping.

Prescribers should:

- Review and advise women to use HRT for as short a time as possible to help reduce the overall risk.
- Advise patients that gradually stopping treatment of HRT may help to reduce the chances of symptoms returning.
- Consider low-dose vaginal estrogens as a therapeutic option for women, where clinically appropriate, as these do not appear to increase breast cancer risk.
- Discuss the updated total risk with women using HRT at their next routine appointment.
- Use the MHRA patients resources provided to support this updated information.
- Only prescribe HRT to relieve post-menopausal symptoms that are adversely affecting quality of life and regularly review patients using HRT to ensure it is used for the shortest time and at the lowest dose.
- Remind current and past HRT users to be vigilant for signs of breast cancer and encourage them to attend for breast screening when invited.

ADRENALINE AUTO-INJECTORS

The MHRA have summarised recent action taken to support safety with adrenaline auto-injectors.

Emerade - activation failure

Some Emerade pens have failed to activate.

Ensure you make contact with patients and their caregivers (as necessary) in possession of Emerade pens to advise them:

- When an Emerade pen is used, it should be pressed firmly against the thigh.
- If administration does not result in activation, a second pen should immediately be used, see letter for patients.
- If there is no improvement in a patients condition and a further dose of adrenaline is needed, additional attempts should be made to administer a pen that has failed to activate, while awaiting the arrival of emergency services.

Emerade pens which are IN-DATE should not be replaced, but patients should be advised to ALWAYS CARRY TWO PENS.

EpiPen and Jext - extended use beyond labelled expiry

To support adequate supply of adrenaline auto-injectors in the UK, an extension by 4 months of the use-by dates has been approved for specific lots of EpiPen 300mcg, Jext 150mcg and 300mcg adrenaline auto-injectors.

Prescribers should:

- Advise patients to carry 2 pens with them at all times.
- Advise patients on the training specific to their device as different brands of adrenaline auto-injector are not used in exactly the same way.
- Show patients and caregivers where to find the lot numbers on their device.
- Encourage patients and caregivers to sign up for the EXPIRY ALERT SERVICE for their specific device on the manufacturers website.
- Keep up-to-date with availability and expiry extensions to specific devices using netFormulary.

MONTELUKAST (Singulair)

Reminder of the risk of neuropsychiatric reactions.

Prescribers should:

- Be alert for neuropsychiatric reactions in patients taking montelukast and carefully consider the benefits and risks of continuing treatment if they occur.
- Advise patients and their caregivers to read the neuropsychiatric reactions in the patient information leaflet and seek medical advice immediately if they should occur.
- Be aware of newly recognised neuropsychiatric reactions of speech impairment (stuttering) and obsessive-compulsive symptoms.

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YELLOW FEVER VACCINE

Stronger precautions in people with weakened immunity and in those aged 60 years or older.

The Commission on Human Medicines has issued a series of recommendations to strengthen measures to minimise risk with the yellow fever vaccine (Stamaril) following very rare fatal reactions.

Advice for healthcare professionals:

- **Yellow fever vaccine is not available on the NHS for travel.**
- Yellow fever vaccine is a highly effective vaccine to protect against life-threatening yellow fever infection; however, strict adherence to contraindications and precautions is essential to reduce the risk of very rare but potentially fatal adverse reactions.
- Key recommendations include new and updated contraindications, strengthened precautions for use in individuals aged 60 years and older, and standardised risk-benefit evaluation procedures across UK yellow fever vaccination centres to ensure that people only receive the vaccine after a thorough risk assessment.
- A letter from MHRA, Public Health England, National Travel Health Network and Centre (NaTHNaC), and Health Protection Scotland has been sent to UK yellow fever vaccination centres to inform them of the recommendations and that changes will be made to the product information and standardised pre-vaccination screening tools.
- Only healthcare professionals specifically trained in benefit-risk evaluation of yellow fever vaccine should administer the vaccine, following their individualised assessment of a person's travel itinerary and suitability to receive the vaccine.
- Every vaccinee should be advised to seek emergency medical attention if they develop signs or symptoms of very rare neurotropic disease (YEL-AND) or viscerotropic disease (YEL-AVD) and should receive the manufacturer's patient information leaflet as part of the travel consultation.

HOSPITAL ONLY MEDICINES

INGENOL MEBUTATE GEL (Picato▼): *Increased incidence of skin tumours seen in some clinical studies.*

This medicine is currently HOSPITAL only but is under review by the Medicines Optimisation Team.

Prescriber should advise patients treated with ingenol mebutate gel to be vigilant for new skin lesions and to seek medical advice immediately should any occur.

NIVOLUMAB (Opdivo): *Reports of cytomegalovirus (CMV) gastrointestinal infection or reactivation.*

Colitis is known to occur commonly in patients treated with nivolumab.

Patients may present in your practice with signs and symptoms of colitis; diarrhoea, blood in stools or abdominal pain. These patients will require further investigation to exclude other causes, including CMV infection.

CARFILZOMIB (Kyprolis▼): *Risk of reactivation of hepatitis B virus.*

It is important that medicines prescribed and supplied directly by secondary care clinicians are recorded and dated on GP clinical systems.

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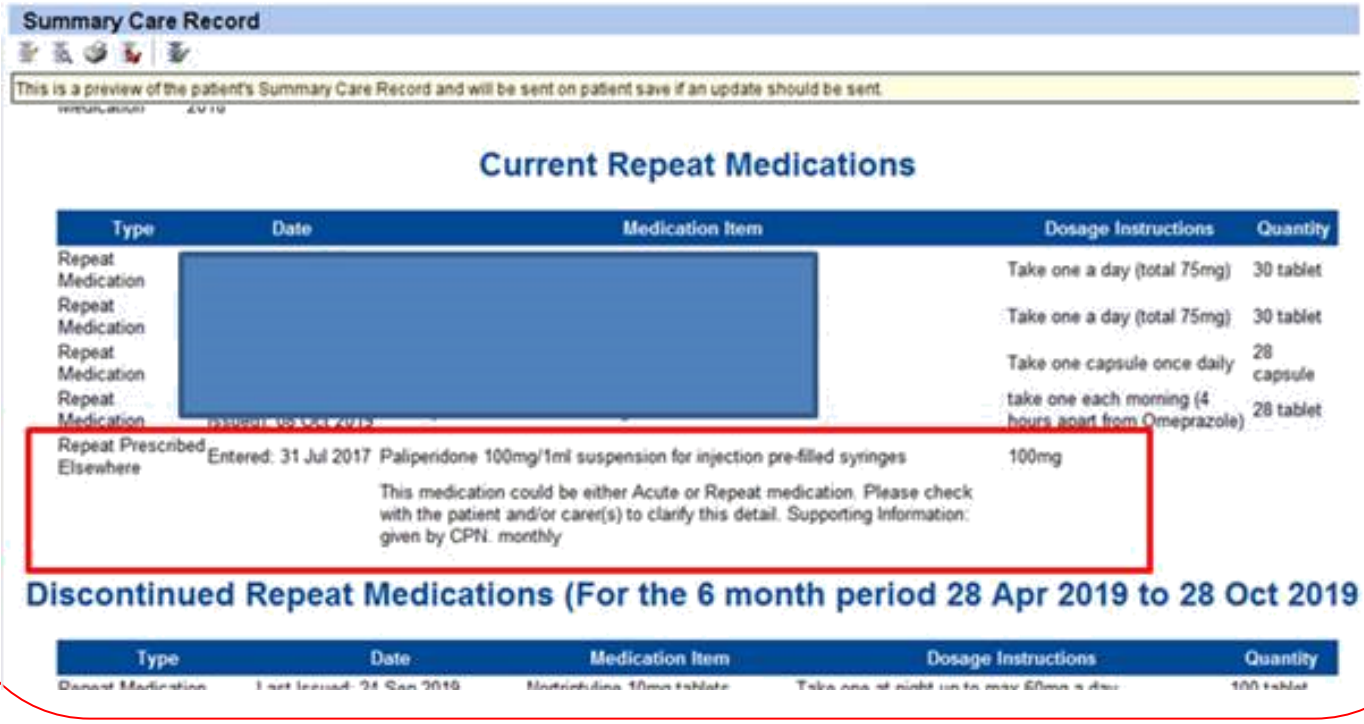
RECORDING HOSPITAL ONLY MEDICINES

GP CLINICAL SYSTEMS AND SUMMARY CARE RECORDS

It is important that medicines prescribed and supplied directly by secondary care clinicians are recorded and dated on GP clinical systems. This will ensure prescribers have all the relevant clinical information available if an adverse reactions is suspected. Information on how to do this for both Systm One and EMIS web can be found on page 6 of the first edition of the Joint Prescribing Group (JPG) newsletter.

This also ensures that these medicines will appear on the patient's **SUMMARY CARE RECORD (SCR).** Where a medicine is recorded as a **HOSPITAL medication** within the GP clinical system it will show on the patient's SCR as medication that is **"PRESCRIBED ELSEWHERE". See screenshot below of how this is captured within a patient's SCR.** It is important that the SCR for the patient is up-to-date to ensure there is safe transfer of care for patients between health sectors.

SUMMARY CARE RECORD SCREENSHOT



DOES YOUR PRACTICE HAVE APPROPRIATE PROCEDURES IN PLACE TO ENSURE THAT ALL CLINICIANS ARE NOTIFIED OF ALERTS URGENTLY AT ALL TIMES?

It is important to review that your current process is fit for purpose especially during periods of annual leave so that all relevant clinical staff are notified of and can action alerts immediately.

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SAFETY SPOTLIGHT

Each newsletter we will provide you with good practice information to support your safe prescribing in practice.

CITALOPRAM AND ESCITALOPRAM - RESTRICTION IN THE ELDERLY

For both citalopram and escitalopram, elderly patients have a higher exposure due to age-related decline in metabolism and elimination. The maximum dose of both medicines has therefore been restricted in patients older than 65 years.

Patients taking concomitant medications known to increase plasma levels of escitalopram and citalopram may require a dose reduction in light of the most recent QT data. Details of specific interactions can be found in individual Summaries of Product Characteristics.

Maximum daily dose schedule is as follows:

*New (restricted) maximum daily dose	Adults	Adults > 65 years	Adults with hepatic impairment
Citalopram	40mg*	20mg*	20mg*
Escitalopram	20mg	10mg*	10mg

LOW MOLECULAR WEIGHT HEPARINS (LMWH)

The Joint Prescribing Group have agreed that across Cambridgeshire and Peterborough for:

- **Paediatric patients, under 16 years of age, who require a LMWH, that both the PRESCRIBING and MONITORING should remain with the HOSPITAL responsible for the patient.**
- **Patients, irrespective of age, requiring administration of a LMWH, where their dose cannot be obtained using a pre-filled syringe, that both the PRESCRIBING and MONITORING should remain with the HOSPITAL responsible for the patient.**

'USING EMOLLIENTS SAFELY' CAMPAIGN HAS LAUNCHED!

Thank you for your support with this campaign so far. Please could you complete the online evaluation to share your thoughts on this patient safety campaign.
Available at: https://www.surveymonkey.co.uk/r/emollientsafety.

FURTHER INFORMATION AND RESOURCES

This campaign includes a range of resources including patient and carer information leaflets, posters, branded pharmacy bags, a communications toolkit and social media assets. You can access these on the related documents tab on the right hand side of the following webpage: http://bit.ly/emollienttoolkit.