

Medicines Safety Assurance Tool

June 2022

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact mlcsu.medicines-safety@nhs.net

Using Proton Pump Inhibitors (PPIs) alongside warfarin – clinical considerations

20 June 2022

This resource considers the management and clinical impact on anticoagulation when prescribing PPI's alongside warfarin. It outlines the evidence and mechanism for the interaction, choosing a suitable PPI, monitoring when initiating and stopping a PPI and counselling points.

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other (please specify)



Action taken

Status

Action due date

Date completed

Metformin and reduced vitamin B12 levels: new advice for monitoring patients at risk

21 June 2022

Vitamin B12 deficiency is now considered a common side effect of metformin, especially in those receiving a higher dose and longer treatment duration, and in those with existing risk factors. Vitamin B12 serum levels should be checked in those with symptoms of deficiency.

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other (please specify)



Action taken

Status

Action due date

Date completed

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Roche Accu-Chek Insight insulin pump with NovoRapid PumpCart insulin cartridges: alert following cases of insulin leakage

21 June 2022

Article discusses a recent National Patient Safety Alert on this topic. The steps outlined in the alert should be actioned, including a review of patients using this pump and a discussion of moving them to an alternative where possible.

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other (please specify)



Action taken

Status	Action due date	Date completed

BNF/BNFC newsletter

24 June 2022

Amongst other significant updates:

- **Colecalciferol**: maximum daily dose added for treatment of vitamin D deficiency.
- **Ergocalciferol**: maximum daily dose added for treatment of vitamin D deficiency.
- **Esketamine** (Spravato®): new requirement to register patients onto Spravato® Register and Alert system.
- **Human papillomavirus vaccine**: updated guidance in-line with UK Health Security Agency recommendations.
- **Influenza vaccine**: updated guidance in-line with UK Health Security Agency recommendations.

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other (please specify)



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Midlands and Lancashire
Commissioning Support Unit

Summary of Product Characteristics (SmPC)

Brilique (ticagrelor) film coated tablets- all strengths

Updated to warn ticagrelor might affect renal excretion of rosuvastatin, increasing risk for rosuvastatin accumulation; exact mechanism is not known, in some cases, concomitant use led to renal function decrease, increased CPK level and rhabdomyolysis.

Cipralax (escitalopram) 5 mg film-coated tablets

SPC updated to note co-administration with serotonergic medicines (e.g. opioids (including tramadol), and triptans (including sumatriptan) may lead to serotonin syndrome; caution is therefore advised if escitalopram is used concomitantly with these medicines.

Duphalac (lactulose) 3.335 g/5 ml Oral Solution

SPC updated to include hypersensitivity and rash, pruritus and urticaria as adverse effects of unknown frequency.

Estradot (estradiol) transdermal patches- all strengths

SPC updated with caution on co-administration with the combination drug regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir and also the regimen glecaprevir/pibrentasvir, due to risk of ALT elevations observed in women using another oestrogen, ethinylestradiol.

Imodium (loperamide) – all formulations

SPC updated to include acute pancreatitis as an adverse effect of unknown frequency.

Imodium (loperamide) 1 mg/5 ml oral solution

The SPC has been updated in line with PRAC advice that a causal relationship between loperamide and acute pancreatitis is at least a reasonable possibility.

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other (please specify)



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Jardiance (empagliflozin) film-coated tablets

SPC updated to include the adverse effect tubulointerstitial nephritis (very rare) and to note empagliflozin may increase renal lithium excretion and decrease blood levels; serum concentration should be monitored more frequently after empagliflozin initiation and dose changes.

Myloxifin (oxycodone hydrochloride, naloxone hydrochloride dehydrate) prolonged-release tablets – all strengths

SPC updated to include warning of risk of developing tolerance and/or physiological dependence upon repeated opioid use. Patients at higher risk of opioid use disorder are those with a personal/family history of substance use/mental health disorders & current tobacco users.

Pancrex V (pancreatin) 340 mg hard capsules

In section 6.4, the specific precautions for storage conditions have changed from "Store at a temperature not exceeding 15°C" to "Store in a refrigerator (2°C - 8°C)".

Plavix (clopidogrel) film-coated tablets

SPC updated to note clopidogrel has been shown to increase rosuvastatin exposure by 2-fold (AUC) and 1.3-fold (Cmax) after administration of a 300mg clopidogrel dose, and by 1.4 fold (AUC) without effect on Cmax after repeated administration of a 75 mg clopidogrel dose.

Progynova (estradiol valerate) 1 and 2 mg tablets

SPC updated with caution on co-administration with the combination drug regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir and also the regimen glecaprevir/pibrentasvir, due to risk of ALT elevations observed in women using another oestrogen, ethinylestradiol.

Reminyl (galantamine hydrobromide) XL prolonged release capsules (all strengths) and solution

SPC updated to include warning that increase in cholinergic tone may worsen symptoms related to extrapyramidal disorders and addition of extrapyramidal disorder as an adverse effect of uncommon frequency.

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Rosuvastatin film-coated tablets – all strengths

The SPC has been updated to contraindicate use of rosuvastatin in patients receiving concomitant combinations of sofosbuvir/velpatasvir/voxilaprevir due to a 7-fold increase in rosuvastatin AUC.

Shingrix powder and suspension for suspension for injection, Herpes zoster vaccine (recombinant, adjuvanted)

SPC now notes an increased risk of Guillain-Barré syndrome (estimated 3 excess cases per million doses administered) was observed following vaccination with Shingrix in a post-marketing observational study. Available information is insufficient to determine a causal relationship.

Teveten (eprosartan) 300 and 600 mg Film-coated Tablets

Trimethoprim containing medicines have been added to list of concomitantly used medicines that may lead to increase in serum potassium.

Tylox (codeine, paracetamol) 30 mg / 500 mg hard capsules

SPC updated to warn of increased risk of high anion gap metabolic acidosis with concomitant use of flucloxacillin, particularly in patients with renal impairment, sepsis, malnutrition and other sources of glutathione deficiency.

Xalacom (latanoprost, timolol maleate) eye drops, solution

SPC updated to include nausea and vomiting as adverse effects

Xalatan (latanoprost) 50 micrograms/ml eye drops solution

SPC updated to include nausea and vomiting as uncommon adverse effects.

Zithromax (azithromycin) 250 mg Capsules

Section 4.6 has been updated to include additional information from observational studies performed in several countries on exposure to azithromycin during pregnancy.

Please note that the information in this Safety log is correct at the time of publication. Clinicians should always refer to the most up to date information.

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About this document

MLCSU collates and shares the latest current awareness and evidence-based medicines information from NICE and UKMi relating to medicines safety each month.

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