

Medicines Safety Assurance Tool

July 2020

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



Midlands and Lancashire
Commissioning Support Unit

[First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review](#)

08 July 2020

This Review was announced by Jeremy Hunt, the then Secretary of State for Health and Social Care in the House of Commons in February 2018. Its purpose is to examine how the healthcare system in England responds to reports about harmful side effects from medicines and medical devices. The review also considers how to respond to them more quickly and effectively in the future.

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

[National Intelligence Report: Early warning scores to detect deterioration in Covid-19 inpatients](#)

30 July 2020

This provides insight into investigation conducted in response to referral highlighting over reliance on early warning scores used in isolation from other indicators of deterioration in a number of NHS trusts when patient admitted to general ward with suspected/confirmed Covid-19.

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Summary of Product Characteristics updates

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[Aldactide \(spironolactone and hydroflumethiazide\) 50mg Tablets](#)

SPC updated to warn sulphonamide like drugs, such as hydroflumethiazide, can cause idiosyncratic reaction resulting in choroidal effusion with visual field defect, transient myopia and acute angle-closure glaucoma, typically occurring within hours to weeks of drug initiation.

[Brintellix \(vortioxetine\) tablets](#)

Aggression/agitation and insomnia have now been highlighted as potential adverse effects of treatment (frequency unknown). Mydriasis has also been reported (rare), and hence caution is advised when using in patients with increased intraocular pressure.

[ChloraPrep \(chlorhexidine gluconate\)](#)

SPC has been revised to warn that chlorhexidine-containing products are known causes of anaphylactic reactions during anaesthesia.

[Co-cyprindiol \(cyproterone acetate/ethinylestradiol\) tablets](#)

SPC notes that co-cyprindiol is: only indicated after menarche, not indicated after menopause and contraindicated in women with severe hepatic disease as long as liver function values have not returned to normal.

[Diflucan \(fluconazole\) preparations](#)

SPC now notes moderate inhibitors of CYP3A4, such as fluconazole, increase plasma ibrutinib concentrations and may increase risk of toxicity. If the combination cannot be avoided, the dose of ibrutinib should be reduced for the duration of the inhibitor use.

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[Kyleena/Jaydess \(levonorgestrel\) 19.5 mg intrauterine delivery system](#)

Dizziness, decreased libido and increased weight have been all reported as common side effects in the updated SPC.

[Levonelle One Step \(levonorgestrel\) tablets \(OTC product\)](#)

SPC has been updated with the inclusion of the age limit of 16 years as this is a requirement for non-prescription use.

[Maxtrex \(methotrexate\) 2.5 and 10 mg Tablets](#)

SPC updated to warn use of nitrous oxide potentiates the effect of methotrexate on folate metabolism, resulting in increased toxicity and whilst this effect can be reduced by administering calcium folinate, the concomitant use of nitrous oxide and methotrexate should be avoided.

[Maxitrol products](#)

SPC now recommends that, because of the possibility of reduced glucose tolerance/diabetes mellitus with topical ophthalmic corticosteroids, caution is recommended when administering maxitrol to patients with a personal or family history of diabetes.

[OxyContin \(oxycodone\) prolonged release tablets](#)

Various updates to SPC include addition of warnings regarding drug dependence, tolerance and potential for abuse, drug withdrawal syndrome, and hyperalgesia, and regarding neonatal withdrawal syndrome and respiratory depression in the newborn when used during pregnancy/labour.

[Pradaxa \(dabigatran\) hard capsules](#)

SPC updated to add 'neutropenia' and 'agranulocytosis' as adverse reactions (frequency not known).

[Strepsils \(Amylmetacresol; 2,4-Dichlorobenzyl alcohol\)](#)

SPC updated to note that hypersensitivity reactions may include angioedema, which may include swelling of the face, neck, throat or tongue that could affect breathing.

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Tetralysal (lymecycline) Capsules

Depression and nightmare have been added to the SPC as potential adverse effects of treatment (frequency unknown).

Topamax (topiramate) – all formulations

Uveitis has been added as an adverse effect (frequency not known).

Vokanamet (canagliflozin/metformin) tablets

SPC now highlights that risk of diabetic ketoacidosis appears to be higher in patients with moderately to severely decreased renal function who require insulin.