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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Medicines Safety Assurance Tool

April 2023

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

NHS Midlands and Lancashire Commissioning Support Unit

Joint BMS FSRH RCGP RCOG SfE and RCN Women's Health Forum safety alert

05 April 2023

Joint safety alert from 6 leading UK health bodies has been published in response to concerns about requests from private clinics to prescribe high doses of oestrogen, outside of product licence & sometimes with insufficient progestogen, for women experiencing menopause symptoms.

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status | Action due date | Date completed

Isotretinoin (Roaccutane▼): new safety measures to be introduced in the coming months, including additional oversight on initiation of treatment for patients under 18 years

26 April 2023

Following advice from an expert working group, the CHM will review implementation of updated recommendations, including requirement for 2 prescribers to agree on the need for treatment when using in those <18 years, and new warnings on psychiatric and sexual side effects.

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status | Action due date | Date completed

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Adrenaline Auto-Injectors (AAIs) safety campaign

25 April 2023

Information for patients, healthcare professionals and wider public to help better understand the importance of AAIs as a potential life-saving medicine covers background of AAIs and provides infographics on the correct use of AAIs during anaphylaxis reactions.

Proposed action

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

Action taken

Status | Action due date | Date completed

Nitrofurantoin: reminder of the risks of pulmonary and hepatic adverse drug reactions

26 April 2023

Healthcare professionals should advise patients to be vigilant for new or worsening respiratory symptoms and symptoms and signs of liver dysfunction while taking nitrofurantoin and promptly investigate any symptoms that may indicate a pulmonary or liver adverse reactions.

Proposed action

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

Action taken

Status | Action due date | Date completed

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Summary of Product Characteristics updates

Proposed action

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

Action taken

Status | Action due date | Date completed

Akizza (ethinylestradiol/gestodene) tablets

SPC contraindicates concomitant use of Akizza with medicinal products containing sofosbuvir/velpatasvir/voxilaprevir owing to ALT elevations. Manufacturers recommend Akizza-users prescribed these treatments must switch to an alternative method of contraception.

Amorolfine nail lacquer preparations

SPC now notes that the product contains 55.2% ethanol, and it includes warnings with respect to being a flammable substance that should not be used near an open flame, a lit cigarette or some devices (e.g. hair dryers).

Daktarin (miconazole) Oral Gel

SPC updated with a warning that the orange flavour (containing: citral, citronellol, linalool, geraniol, d-limonene) and cocoa flavour (containing benzyl alcohol, benzyl benzoate) may cause allergic reactions.

Dexamfetamine Sulfate 1 mg/ ml Oral Solution

SPC updated to note that dexamfetamine is in part metabolised via CYP2D6. Although the clinical significance of this interaction is likely to be minimal, attention should be paid when medications metabolised by these pathways are administered.

Flucelvax Tetra (influenza virus surface antigens) vaccine

SPC updated with Guillain-Barre syndrome as an adverse drug reaction (frequency not known).

Lipitor (atorvastatin) 80 mg film-coated tablets

SPC updated to note that in a few cases, statins have been reported to induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia, and that treatment should be discontinued in case of aggravation of symptoms.

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MicardisPlus (telmisartan/ hydrochlorothiazide) tablets

SPC updated with warnings relating to very rare severe cases of acute respiratory toxicity, including acute respiratory distress syndrome (ARDS) reported after taking hydrochlorothiazide. If ARDS is suspected, MicardisPlus should be withdrawn, and appropriate treatment given.

Naseptin (Chlorhexidine and neomycin) Nasal Cream

This product has now been reformulated with medium chain triglycerides replacing the arachis oil (peanut oil) excipient. Contra-indications for use in patients with peanut and/or soya have therefore been removed.

Omeprazole preparations

Acute tubulointerstitial nephritis has been added as a rare potential adverse effect. It may occur at any point during therapy and can progress to renal failure. Omeprazole should be discontinued in case of suspected cases, and appropriate treatment promptly initiated.

Rilutek (riluzole) 50 mg film-coated tablets

Rash has been added as a potential adverse effect of treatment (frequency unknown).

Zlatal (methotrexate) solution for injection in pre-filled syringe

SPC now notes that, in treatment of males, the precautionary measure of reliable contraception that should continue after treatment has been reduced to 3 months. Other brands of methotrexate injection currently still recommend 6 months of contraception after treatment cessation.

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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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