Medicines Safety Assurance Tool
June 2019

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

Direct-acting oral anticoagulants (DOACs): increased risk of recurrent thrombotic events in patients with antiphospholipid syndrome

Medicines and Healthcare products Regulatory Agency | 20 June 2019

MHRA advises that DOACs are not recommended in patients with antiphospholipid syndrome, particularly high-risk patients (those who test positive for all 3 antiphospholipid tests — lupus anticoagulant, anticardiolipin antibodies, and anti-beta 2 glycoprotein I antibodies).

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

GLP-1 receptor agonists: reports of diabetic ketoacidosis when concomitant insulin was rapidly reduced or discontinued

Medicines and Healthcare products Regulatory Agency | 20 June 2019

It is advised that blood glucose self-monitoring is necessary when adjusting the dose of insulin, particularly when GLP-1 receptor agonist therapy is initiated, and insulin is reduced. Any insulin dose reduction should be done in a stepwise manner.

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Oral retinoid medicines?: revised and simplified pregnancy prevention educational materials for healthcare professionals and women

Medicines and Healthcare products Regulatory Agency | 20 June 2019

New prescriber checklists, patient reminder cards, and pharmacy checklists are available to support Pregnancy Prevention Programme in women on acitretin, alitretinoin and isotretinoin. Advice about risk of neuropsychiatric reactions has been made consistent for all oral retinoids.

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Registration of GP Practices with the Central Alerting System

Medicines and Healthcare products Regulatory Agency | 24 Jun

In support of improving patient safety alerting system resilience for general practice, there are new contractual requirements for practices to register a practice email address with the CAS by 01 October 2019, and monitor the email account to act on CAS alerts where appropriate.

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Falsified Medicines Directive Alert Class 2, Action Within 48 Hours, B &Amp; S Healthcare, Multiple Parallel Imported Products.

Central Alerting System | 27 June 2019

Recall of medicines that have been taken out of the regulated medicines supply chain during distribution and later re-introduced. The products were parallel imported into the UK from Italy by B & S Healthcare. The products are believed to be legitimate medicines.

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Summary of Product Characteristics Update

Electronic Medicines Compendium | June 2019

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Brilique (ticagrelor) tablets

Thrombotic thrombocytopenic purpura has been added to the SPC as a potential adverse effect of treatment (frequency unknown)

Cozaar (losartan) oral suspension and film-coated tablets

Sections 4.4 and 4.5 of the SPC now advise the concomitant use of 'other drugs that may increase serum potassium (e.g. trimethoprim-containing products)' is not recommended.

Cozaar-Comp (losartan with hydrochlorothiazide) film-coated tablets

Sections 4.4 and 4.5 of the SPC now advise concomitant use of other drugs that may increase serum potassium (e.g. trimethoprim-containing products) is not recommended. Also, an increased risk of non-melanoma skin cancer with cumulative dose of hydrochlorothiazide exposure has been observed.

Rythmodan (disopyramide phosphate) Retard 250mg Modified Release Tablets

The SPC advises that the sustained release formulation is contra-indicated in children.

Levonelle (levonorgestrel) One Step/ 1500 microgram tablet

The SPC has been updated with new pharmacokinetic data in obese women and BMI impact on efficacy.

Maxtrex (methotrexate) 2.5 mg tablets

Thoracic pain has been added as an adverse event (frequency not specified) to the SPC.

Salofalk (mesalazine) 500mg gastro-resistant tablets

The SPC has been updated with information about sodium content: This medicinal product contains 49 mg sodium per tablet, equivalent to 2.5% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Movicol (macrogol) preparations

The SPC has been updated following a PRAC recommendation to highlight that Movicol is considered high in sodium, and that this should be particularly taken into account for those on a low salt diet.

Xarelto (rivaroxaban) film-coated tablets

The SPC has been updated in line with PRAC recommendations to advise DOACs, including rivaroxaban, are not recommended for patients with a history of thrombosis who are diagnosed with antiphospholipid syndrome, in particular for patients that are triple positive.

Yemex (fentanyl) 12 microgram/hour Transdermal Patch

The SPC has been revised to include androgen deficiency as an endocrine system disorder adverse effect of unknown frequency.