Medicines Safety Assurance Tool

March 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

NHS
Midlands and Lancashire
Commissioning Support Unit

Administration of tobramycin via a nebuliser

12 March 2020

If it is necessary to administer tobramycin injection via nebuliser instead of licensed nebuliser solution then it is critical a phenol-free formulation of injection is used. This document outlines risks linked to using injection instead of nebuliser solution for this indication.

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☑ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Pharmacovigilance Risk Assessment Committee (PRAC) recommends suspension of ulipristal acetate for uterine fibroids during ongoing EMA review of liver injury risk

16 March 2020

The safety committee of the EMA has advised that all women taking 5-mg ulipristal acetate should be advised to stop taking it, whilst a safety review is started following a further report of serious liver injury leading to the need for liver transplantation.

Proposed action

☑ Newsletter ☑ Optimise Rx/ScriptSwitch

☑ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

SGLT2 inhibitors: monitor ketones in blood during treatment interruption for surgical procedures or acute serious medical illness

18 March 2020

SGLT2 inhibitor treatment should be interrupted in patients who are hospitalised for major surgical procedures or acute serious medical illnesses and ketone levels measured, preferably in blood rather than urine.

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Benzodiazepines and opioids: reminder of risk of potentially fatal respiratory depression

18 March 2020

Benzodiazepines and opioids can both cause respiratory depression, which can be fatal if not recognised in time. Only prescribe together if there is no alternative and closely monitor patients for signs of respiratory depression.

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

CHMP recommend no change to market authorisation follow study assessing serious bleeding risk of DOACs

30 March 2020

Following a review of real world data, the CHMP concluded that the pattern of serious bleeding seen in patients taking apixaban, dabigatran and rivaroxaban was similar to that seen in clinical trials on which the market authorisation were based.

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 updates

March 2020

BOTOX (botulinum toxin type A) 100 and 200 Units Powder for solution for injection

In section 4.2, the method of administration was updated from physicians to an appropriately qualified healthcare practitioner with expertise in the treatment of the relevant indication and the use of the required equipment, in accordance with national guidelines.

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

Action taken

Status: Unassigned | Action due date | Date completed

Brintellix (vortioxetine) film-coated tablets- all strengths

SPCs have been revised to state that in clinical studies, sexual dysfunction was assessed using the Arizona Sexual Experience Scale (ASEX) and doses of 5 to 15mg showed no difference to placebo. However, the 20 mg dose was associated with an increase in sexual dysfunction.

Dalacin C Phosphate (clindamycin) Sterile Solution

Information on hypersensitivity and severe skin reaction added to SPC, as has text on drug interaction with CYP450 3A4 inducers including rifampicin, and following ADRs: anaphylactic shock/reaction, hypotension, oesophageal ulcers, oesophagitis and abnormal LFTs.

Dioralyte Sachets (all presentations)

Includes updated statement on cases where electrolyte balance may be disturbed and advice that patients on low potassium and sodium diets need medical supervision. Overdose section now mentions cases of severe hepatic or renal failure. New warnings and precautions have been added, including not to use in infants <24 months without medical supervision, and that medical supervision is recommended for use during pregnancy and lactation. New wording regarding hypersensitivity has been added to the contraindications.

Emerade (adrenaline) solution for injection in pre-filled pen – all strengths

Section 4.2 states Emerade should be administered at first sign of anaphylaxis. Section 4.4 warns in patients with a thick subcutaneous fat layer, there is risk of adrenaline being administered in fat tissue which may result in suboptimal effect and need for a second dose.

Efexor XL (venlafaxine) hard prolonged release capsules – all strengths

Section 4.8 has been updated with the addition of adverse drug reaction ‘takotsubo cardiomyopathy’.

Feldene Melt (piroxicam) 20mg Tablets

Information with NSAIDs regarding the increased risk of serious gastrointestinal events, and the adverse effect of glomerulonephritis (unknown frequency) have been added to the SPC.

Feraccru (iron maltol) 30mg hard capsules

The SPC now advises no dose adjustment is needed in elderly patients or patients with renal impairment (eGFR ≥15 ml/min/1.73 m2).

Immodium (loperamide) preparations

SPC now details that overdose can unmask existing Brugada syndrome. Therefore patients should not exceed the recommended dose and/or the recommended duration of treatment.

Lamictal (lamotrigine) tablets and dispersible tablets

Section 4.4 now states both Lamictal tablets and Lamictal chewable/ dispersible tablets contain less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium free'.

Mirapexin (pramipexole) tablets (all strengths and presentations)

Sections 4.2 and 4.4 now advise abrupt discontinuation of dopaminergic therapy can lead to the development of a neuroleptic malignant syndrome or a dopamine agonist withdrawal syndrome.

Nasonex (mometasone furoate monohydrate) 50 micrograms/actuation nasal spray suspension

SPC revised to warn nasal spray contains benzalkonium chloride which may cause nasal irritation or swelling inside the nose, especially if used for a long time.

Nebido (testosterone undecanoate) 1000mg/4ml, solution for injection

Section 4.4 has been updated with warnings on drug abuse and dependence.

Neoclarityn (desloratadine) 5 mg film-coated tablets and oral solution

Undesirable effects section updated to reflect increased incidence of new-onset seizure in patients age 0 to 19 years when receiving desloratadine compared with periods not receiving desloratadine based on the results of the final report from a study.

Onglyza (saxagliptin hydrochloride) film-coated tablets – all strengths

SPCs warn that if a patient develops blisters/erosions while receiving saxagliptin and bullous pemphigoid is suspected, this medicinal product should be discontinued and referral to a dermatologist should be considered for diagnosis and appropriate treatment.

Qtern (saxagliptin hydrochloride, dapagliflozin propanediol monohydrate) 5mg/10mg film-coated tablets

SPC now advises discontinuation of treatment if GFR falls persistently below 45mL/min and warns if a patient develops blisters and bullous pemphigoid is suspected, Qtern should be discontinued and patient referred to dermatologist.

Sacubitril (vigabatrin) film-coated tablets and granules for oral solution

Section 4.4 and 4.8 have been updated with further information on risk of reduced visual acuity, and advice that both visual field testing and assessment of visual acuity should be done at treatment initiation and continued at 6 month intervals for whole duration of treatment.

Suliqua (lixisenatide and insulin glargine) in a pre-filled pen

SPC now details that lipodystrophy and cutaneous amyloidosis may occur at the injection site of insulins and delay local insulin absorption. Continuous rotation of the injection site within the given injection area may help to reduce or prevent these reactions.

Zestoretic (Lisinopril and hydrochlorthiazide) tablets

SPC now advises that Zestoretic should not be taken within 36 hours of the last dose of sacubitril/valsartan due to increased risk of angioedema.

Zyprexa (olanzapine) preparations

Salivary hypersecretion has been added as a potential adverse effect of treatment (frequency uncommon).

Zofran (ondansetron) Tablets- all presentations

Section 4.6 has been updated to include information about the increased risk of ondansetron causing oral clefts (3 additional cases per 10 000 women treated; adjusted relative risk, 1.24, (95% CI 1.03-1.48).