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Medicines Safety Assurance Tool October 2018

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Midlands and Lancashire
Commissioning Support Unit

CoaguChek Test Strips for Point of Care and Home Use - risk of false high results

Central Alerting System | 08 October 2018

The manufacturer Roche Diagnostics GmbH has issued an alert stating that affected CoaguChek test strips may give false high results for INR values above 4.5 when compared to laboratory results which may lead to incorrect treatment decisions.

<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102801>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Ritonavir-containing products: reports of interaction with levothyroxine leading to reduced thyroxine levels

Medicines and Healthcare products Regulatory Agency | 11 October 2018

The MHRA advises that thyroid-stimulating hormone should be monitored in patients treated with levothyroxine for at least the first month after starting and ending ritonavir. This interaction has been added to SPCs and PILs for ritonavir-containing medicines and levothyroxine.

<https://www.gov.uk/drug-safety-update/ritonavir-containing-products-reports-of-interaction-with-levothyroxine-leading-to-reduced-thyroxine-levels>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Transdermal fentanyl patches: life-threatening and fatal opioid toxicity from accidental exposure, particularly

Medicines and Healthcare products Regulatory Agency | 11 October 2018

The MHRA continues to receive reports of unintentional opioid toxicity and overdose of fentanyl due to accidental exposure (AE) to patches. Patients/caregivers should be given clear information about how to minimise risk of AE and importance of appropriate disposal of patches.

<https://www.gov.uk/drug-safety-update/transdermal-fentanyl-patches-life-threatening-and-fatal-opioid-toxicity-from-accidental-exposure-particularly-in-children>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Double check patients with 'penicillin allergy' to avoid increased MRSA risk

National Institute for Health and Care Excellence | 31 Oct 2018

Healthcare staff should be aware of this and ensure that only people with a true allergy to penicillin are documented as such, NICE is urging. Incorrectly identifying people as allergic could also contribute to antimicrobial resistance, as these people are likely to instead be given broad-spectrum antibiotics.

https://www.nice.org.uk/news/article/double-check-patients-with-penicillin-allergy-to-avoid-increased-mrsa-risk?utm_medium=email&utm_source=nicenewsletter&utm_campaign=penicillinallergycheck

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 | October 2018

Acnecide (hydrous benzoyl peroxide) 5% w/w Wash

Section 4.4 of the SPC has been updated to include a warning that this product may cause swelling and/or blistering of the skin.

<https://www.medicines.org.uk/emc/product/3274/smpc>

Brancico XL (quetiapine) tablets

The SPC now states that severe cutaneous adverse reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms have been reported in association with quetiapine treatment. It has a frequency of very rare or unknown frequency.

<https://www.medicines.org.uk/emc/product/7391/smpc>

Bramox (midodrine) 5 mg tablets

The SPC now notes patients taking midodrine may have falsely elevated plasma metanephrine and this potential for interference should be considered where patients taking it require biochemical investigation for potential pheochromocytomas and paragangliomas.

<https://www.medicines.org.uk/emc/product/2268/smpc>

Celectol (celiprolol) 200mg Tablets

The SPC has been revised to warn that an increased risk of depression has been reported when beta blockers are co-administered with diltiazem.

<https://www.medicines.org.uk/emc/product/9241/smpc>

Depakote (valproate semisodium) 500mg Tablets

Urinary incontinence has been added to the SPC as a common undesirable effect.

<https://www.medicines.org.uk/emc/product/6113/smpc>

Diflucan (fluconazole) products

The SPC now advises exposure of tofacitinib is increased when co-administered with drugs that result in both moderate inhibition of CYP3A4 and strong inhibition of CYP2C19 (e.g. fluconazole) thus tofacitinib dose should be reduced to 5mg once daily when combined with these drugs.

<https://www.medicines.org.uk/emc/product/2783/smpc>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Efexor (venlafaxine) products

SPCs now state that false-positive urine immunoassay screening tests for amphetamine have been reported in patients taking venlafaxine and risk of serotonin syndrome may occur with concomitant use of amphetamines.

<https://www.medicines.org.uk/emc/product/5474/smpc>

Epilim (sodium valproate) preparations

Urinary incontinence has been added as a common undesirable effect to the SPC.

<https://www.medicines.org.uk/emc/product/1446/smpc>

Faverin (fluvoxamine) tablets

Aggression has been added as an uncommon adverse effect of treatment to the SPC.

<https://www.medicines.org.uk/emc/product/1169/smpc>

Fentanyl Effentora Buccal Tablets (all strengths)

The SPC now warns that concomitant use of opioids with sedative medicines such as benzodiazepines or related drugs increases risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited.

<https://www.medicines.org.uk/emc/product/5402/smpc>

Flagyl (metronidazole) products

SPCs now warn cases of severe bullous skin reactions such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) or acute generalised exanthematous pustulosis (AGEP) have been reported. If symptoms/signs are present, treatment must be immediately discontinued.

<https://www.medicines.org.uk/emc/product/9237/smpc>

Fluvastatin capsules

Diarrhoea has been added as a potential adverse effect of treatment (frequency unknown) to the SPC.

<https://www.medicines.org.uk/emc/product/4465/smpc>

Fostair (beclomethasone and formoterol) NEXThaler 100/6

The SPC has been updated to add maintenance and reliever treatment (MART) posology in asthma. The MART regimen is in line with the Fostair 100/6 aerosol device (1 puff as needed as rescue treatment, up to a maximum daily dose of 8 inhalations).

<https://www.medicines.org.uk/emc/product/3317/smpc>

Indocid (indomethacin) suppositories

The SPC no longer makes specific dosing recommendations in dysmenorrhea and gouty arthritis; it now states that dosage should be carefully adjusted to suit the needs of the individual patient. Updated info has been added on use in third-trimester of pregnancy.

<https://www.medicines.org.uk/emc/product/2946/smpc>

Kyleena (levonorgestrel) 19.5 mg intrauterine delivery system

The SPC has been revised to warn that cases of hypersensitivity including rash, urticaria and angioedema have been reported with use of levonorgestrel intrauterine system.

<https://www.medicines.org.uk/emc/product/769/smpc>

Lyclear (permethrin) products

SPCs have been updated and now state limited experience in children aged >6 months to 3 years thus treatment should be under close specialist supervision. In case of hypersensitivity to chrysanthemums/other compositae, a chemically different treatment should be used. Paraesthesia has been added as ADR.

<https://www.medicines.org.uk/emc/product/5458/smpc>

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

Section 6.6 of the SPC has been updated to state if this oil-based product is stored at cold temperature; properties may temporarily change and so the product should be brought to room or body temperature before use. Sections 2 and 4.4 updated to include the excipient benzyl benzoate.

<https://www.medicines.org.uk/emc/product/3873/smpc>

Nicorette Quickmist 1mg/spray mouthspray and Cool Berry 1mg/spray mouthspray

Sections 2 and 4.4 of the SPC has been updated to include the presence of a small amount of butylated hydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

<https://www.medicines.org.uk/emc/product/5956/smpc>

Seroquel (quetiapine) film-coated tablets (all presentations)

Severe cutaneous adverse reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, have been added as adverse effects to SPC.

<https://www.medicines.org.uk/emc/product/7553/smpc>

Singulair (montelukast) tablets

Thrombocytopenia (very rare), tic (rare) and enuresis in children (uncommon) have been added as undesirable effects to the SPC.

<https://www.medicines.org.uk/emc/product/197/smpc>

Tiotropium (Braltus) 10mcg Inhalation Powder

Advice in SPC had been strengthened to ensure patients follow instructions carefully in PIL and be aware of extra pictures on inside of lid of carton showing correct method for inserting capsule into inhaler and never placing it directly into mouthpiece, to avoid risk of choking.

<https://www.medicines.org.uk/emc/product/4446/smpc>

Zonisamide Endo (zonisamide) capsules (all strengths)

Sections 4.4 and 4.6 of the SPC now warn Zonisamide must not be used in women of childbearing potential not using contraception unless potential benefit justifies risk to the foetus. Data suggest increased rates of babies born at low birth weight, pre-term or small for gestational age.

<https://www.medicines.org.uk/emc/product/9339/smpc>