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Medicines Safety Assurance Tool June 2018

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Midlands and Lancashire
Commissioning Support Unit

European CHMP endorses measures to reduce risk of liver injury with ulipristal acetate (Esmya)

European Medicines Agency | 04 June 2018

New measures have been placed to highlight contraindications in liver problems. It is advised to do liver tests before, during and after stopping treatment. There should be a patient card detailing liver monitoring and to contact GP if symptomatic.

Additionally, use of for more than one treatment course is restricted to women not eligible for surgery.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/06/

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Can small volume intramuscular injections be given to patients taking oral anticoagulants?

Specialist Pharmacy Service | 12 June 2018

Q+A notes most of published studies relate to IM influenza vaccination in patients on older anticoagulants. Data are limited, and some findings are contradictory. There is very little published information about the risks of adverse effects with DOACs and IM injections.

<https://www.sps.nhs.uk/articles/can-small-volume-intramuscular-injections-be-given-to-patients-taking-oral-anticoagulants/>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

What factors need to be considered when dosing patients with renal impairment?

Specialist Pharmacy Service | 18 June 2018

This article discusses the pharmacokinetic and pharmacodynamic factors that affect dosing in renal impairment.

https://www.sps.nhs.uk/wp-content/uploads/2018/06/SW-QA-Dosing_in_RI-2018.docx

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Resources to support safer modification of food and drink

Central Alerting System | 27 June 2018

This alert has been released to highlight the variation in the terminology used to describe the thickness of modified food for patients with dysphagia.

<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102767>

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 2018

Coversyl Arginine (perindopril arginine)

New contraindications (bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney, extracorporeal treatments and use with sacubitril/valsartan), and an interaction with co-trimoxazole (concomitant use may increase risk of hyperkalaemia).

<https://www.medicines.org.uk/emc/product/6224/smpc>

Eliquis (apixaban) 2.5mg film-coated tablets

The SPC has been updated to state that 'apixaban can be initiated or continued in NVAf patients who may require cardioversion'. Information has also been added to include detail on dose in relation to cardioversion. Data from the EMANATE study (conducted in patients undergoing cardioversion) has been added.

<https://www.medicines.org.uk/emc/product/4756/smpc>

Epilim/Zentiva (valproate) healthcare professional letter

The letter sets out new contraindications, warnings and measures from the EMA and MHRA to prevent valproate exposure during pregnancy.

<https://www.medicines.org.uk/emc/rmm/1231/Document>

Hiprex (methenamine) tablets

It has been noted that methenamine affects the urine test results when testing for steroids, catecholamines and 5 hydroxyindole acetic acid and that it is preferred to avoid it during pregnancy as a precaution. Side effects of diarrhoea and abdominal pain have been added.

<https://www.medicines.org.uk/emc/product/1530/smpc>

Invokana (canagliflozin) 100mg and 300mg film coated tablets

SPC has included study data which has evaluated canagliflozin in combination with metformin and sitagliptin and a study also done to evaluate it in combination with metformin XR.

<https://www.medicines.org.uk/emc/product/8855/smpc>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed



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Grey rectangular box for date completed.

Ipidine (apraclonidine) 5mg/ml eye drops, solution

Hypersensitivity and eyelid disorder have been added as adverse drug reactions.

<https://www.medicines.org.uk/emc/product/838/smpc>

Janumet (sitagliptin and metformin) tablets

Adverse effect of thrombocytopenia has been added as a rare potential effect.

<https://www.medicines.org.uk/emc/product/564/smpc>

Januvia (sitagliptin)

Thrombocytopenia has been added as a rare adverse event.

<https://www.medicines.org.uk/emc/product/321/smpc>

Ketovite tablets

Anaphylactic reaction has been added to SPC as an adverse effect of unknown frequency.

<https://www.medicines.org.uk/emc/product/1052/smpc>

Nurofen for Children (ibuprofen; various products)

Adverse drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) has been added as an adverse effect, with the frequency unknown.

<https://www.medicines.org.uk/emc/product/396/smpc>

PecFent (fentanyl citrate)

The SPC states that there is a possibility of hyperalgesia, tolerance and progression of disease should be considered in the absence of adequate pain control. Drug dependence and neonatal withdrawal syndrome have been added as unknown frequency adverse drug reactions.

<https://www.medicines.org.uk/emc/product/5782/smpc>

Propecia (finasteride) 1mg tablets

An adverse reaction of anxiety has been added as an unknown frequency.

<https://www.medicines.org.uk/emc/product/2194/smpc>

Proscar (finasteride) 5mg film coated tablets

An adverse drug reaction of 'anxiety' of unknown frequency has been added to SPC.

<https://www.medicines.org.uk/emc/product/1008/smpc>

Scheriproct ointment and suppositories

There is a new warning that the following excipients in ointment and suppositories may reduce the effectiveness of latex products such as condoms; castor oil refined, castor oil hydrogenated, macrogol-400-monoricinoleate and perfume oil chypre.

<https://www.medicines.org.uk/emc/product/283/smpc>

Siklos (hydroxycarbamide) Film coated tablets – all strengths

Section 4.8 now warns systemic and cutaneous lupus erythematosus as very rare adverse reactions.

<https://www.medicines.org.uk/emc/product/4033/smpc>

Starlix (nateglinide) 60mg film coated tablets

SPC has been updated to state that patients with severe renal impairment who have not undergone haemodialysis, are more susceptible to its glucose-lowering effect. Therefore, discontinuation of the product should be considered in patients with severe renal impairment who present with potentiation of the hypoglycaemic event.

<https://www.medicines.org.uk/emc/product/1320/smpc>

Symbicort (budesonide and formoterol fumarate) pressurised inhalation, suspension

Instructions and pharmacokinetic data for when Symbicort is used with a spacer device has been updated on the SPC.

<https://www.medicines.org.uk/emc/product/7223/smpc>

Education Risk Minimisation Materials to help reduce the risk associated with using Truvada (tenofovir disoproxil fumarate/emtricitabine) film coated tablets

This guidance document has been amended to include advice specific to adolescents following extension to indication for use with safer sex practices for PrEP in those at high risk aged 12 years and above, weighing 35kg or more.

<https://www.medicines.org.uk/emc/product/3890/rmms>

Valcyte (valganciclovir) 450mg film coated tablets

The SPC has included information on a small clinical study that evaluated the effect of valganciclovir on spermatogenesis and noted that a higher risk of cytopenia in neonates and infants requires careful monitoring of blood counts in these age groups.

<https://www.medicines.org.uk/emc/product/1641/smpc>

Vipidia (alogliptin) tablets

Diarrhoea has been added as a common potential adverse effect.

<https://www.medicines.org.uk/emc/product/5235/smpc>

Zidoval (metronidazole) vaginal gel

It has been noted that metronidazole has found to be carcinogenic in certain animal species, however, this has not been established in human. The effect of topical metronidazole on prothrombin time is also not known.

<https://www.medicines.org.uk/emc/product/830/smpc>

Zirtek Allergy (cetirizine) 10mg film coated tablets

An adverse effect of Hepatitis has been added with unknown frequency

<https://www.medicines.org.uk/emc/product/6751/smpc>

Zithromax (Azithromycin) – all formulations

An interaction with colchicine has been added; concomitant administration has been reported to result in increased serum levels of the P-glycoprotein substrate.

<https://www.medicines.org.uk/emc/product/9205/smpc>