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Medicines Safety Assurance Tool August 2018

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Midlands and Lancashire
Commissioning Support Unit

Esmya (Ulipristal Acetate) For Symptoms of Uterine Fibroids: Restrictions To Use And Requirement To Check Liver Function Before, During And After Treatment

Medicines and Health Products Regulatory | 07 August 2018

This alert has been established to advise that with immediate effect, Esmya should not be used unless new restricted indication is met, and patient does not have an underlying liver disorder; more than one treatment course is now authorised only in women who are not eligible for surgery following the completion of an EU review to investigate the link between Esmya and cases of serious liver injury.

<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102786>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Resources to support safe and timely management of hyperkalaemia

NHS Improvement | 08 Aug 2018

Several resources are included for organisations to ensure staff have access to information to guide prompt and appropriate investigation and treatment. Resources include the UK Renal Association guidelines for acute hyperkalaemia in adults and Resuscitation Council guidelines

<https://improvement.nhs.uk/resources/resources-to-support-safe-and-timely-management-of-hyperkalaemia/>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Updated restrictions on use of Varicella Zoster Immunoglobulin (VZIG) during supply shortage: advice to health

Public Health England | 09 August 2018

This updated guidance includes the extension of the restriction of VZIG to include all immunosuppressed individuals except for those where oral aciclovir/valganciclovir may be contraindicated; and strengthening guidance on the use of aciclovir in susceptible women with exposure from week 20 of pregnancy.

<https://www.gov.uk/government/publications/varicella-zoster-immunoglobulin>

Proposed action 

Newsletter Optimise Rx/ScriptSwitch

Practice audit/search Other (please specify)

Action taken

Status Action due date Date completed

Unassigned ▼ _____

Title of the safety alert that may end up wrapping

Electronic Medicines Compendium | August 2018

Brilique (ticagrelor) products

The timing of discontinuation of ticagrelor prior to elective surgery has been updated from 7 to 5 days.

<https://www.medicines.org.uk/emc/product/5767/smpc>

Brintellix (vortioxetine) tablets 5, 10 and 20mg

Angioedema and urticaria have been added to the table of undesirable effects (frequency not known).

<https://www.medicines.org.uk/emc/product/7121/smpc>

Champix (varenicline) 0.5 and 1.0 mg film-coated tablets

Transient loss of consciousness has been added to SPC as adverse effect.

<https://www.medicines.org.uk/emc/product/266/smpc>

Dovobet (calcipotriol and betamethasone) preparations

SPC has been updated to state that visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with visual disturbances (e.g. blurred vision) they should be considered for referral to an ophthalmologist.

<https://www.medicines.org.uk/emc/product/5690/smpc>

Proposed action 

Newsletter Optimise Rx/ScriptSwitch

Practice audit/search Other (please specify)

Action taken

Status Action due date Date completed

Unassigned ▼ _____

Eliquis (apixaban) 2.5 mg film-coated tablets

The SPC has been updated to advise that care should be taken if patients are treated concomitantly with SSRIs or SNRIs, due to the increased bleeding risk.

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

Esmya (ulipristal acetate) 5mg tablets

Posology has been revised to one course of pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The SPC also now states that treatment should only be in women who are not eligible for surgery.

<https://www.medicines.org.uk/emc/product/3951/smpc>

Fucidin (sodium fusidate) Tablets

The SPC has been updated to note that a few cases of serious cutaneous reactions (e.g. DRESS syndrome, toxic epidermal necrolysis and Stevens-Johnson syndrome) have been reported with systemic sodium fusidate, usually appearing in the first weeks of treatment.

<https://www.medicines.org.uk/emc/product/5515/smpc>

Humulin (human insulin) cartridge preparations

The updated SPC now states that insulin from Humulin cartridges is only suitable for subcutaneous administration, and that cartridges should only be used in a Lily reusable pen as the dosing accuracy has not been established with other pens.

<https://www.medicines.org.uk/emc/product/8195/smpc>

Lariam (mefloquine)

Materials include a guide for healthcare professionals on side effects (especially neuropsychiatric), a checklist that should always be used when prescribing and supplying mefloquine chemoprophylaxis, and a Patient Alert Card (enclosed in the product package).

<https://www.medicines.org.uk/emc/product/1108/rmms>

Lustral (sertraline) 50mg film coated tablets

Rhabdomyolysis has been added to SPC as adverse effect, as has amphetamine to the list of other interacting serotonergic drugs.

<https://www.medicines.org.uk/emc/product/1070/smpc>

Mupirocin 20 mg/g ointment

SPC now warns that butylated hydroxytoluene, an excipient, may cause local skin reactions (e. g. contact dermatitis), or irritation to the eyes and mucous membranes.

<https://www.medicines.org.uk/emc/product/5405/smpc>

Myfortic gastro-resistant tabs (mycophenolic acid as mycophenolate sodium)

Additional warning and precautions for use in relation to contraception in men and women because of robust clinical evidence showing a high risk of abortion and congenital malformations when used in pregnancy.

<https://www.medicines.org.uk/emc/product/7793/smpc>

Nasacort Allergy Nasal Spray (triamcinolone acetonide)

Chorioretinopathy and blurred vision have been added as adverse effects. The general statement and advice regarding reports of visual disturbance associated with systemic and topical corticosteroid use has been added.

<https://www.medicines.org.uk/emc/product/6501/smpc>

Risperdal (risperidone) preparations

Somnambulism and sleep related eating disorder (frequency rare) have been added as adverse events to the SPC.

<https://www.medicines.org.uk/emc/product/1690/smpc>

Seroquel XL (quetiapine) prolonged-release tablets

Stroke has been added as an undesirable effect to the SPC. The warnings/precautions section has been updated to include information on increased risk of self-harm and suicide in patients aged 25-64 years, and to advice caution when prescribing to elderly patients with Parkinson's disease.

<https://www.medicines.org.uk/emc/product/6363/smpc>

Shortec (oxycodone hydrochloride)

SPC now advises that where there is concomitant use of opioids with sedative medicines such as benzodiazepines; the dose and duration of concomitant use should be limited.

<https://www.medicines.org.uk/emc/product/2383/smpc>

Solu-Medrone

Blurred vision has been added as a rare adverse effect to SPCs.

<https://www.medicines.org.uk/emc/product/1550/smpc>

Tetralysal (lymecycline)

SPC has been updated with new age contraindication from 12 years to 8 years.

<https://www.medicines.org.uk/emc/product/926/smpc>

Xarelto (rivaroxaban) 2.5 mg film-coated tablets

DRESS syndrome and anaphylactic reactions have been added to SPC as adverse effects. SPC has been amended to advise interaction with fluconazole/erythromycin/clarithromycin is likely not clinically relevant in most patients but can be potentially significant in high-risk patients.

SPC revised to include a new indication; co-administration with acetylsalicylic acid for the prevention of atherothrombotic events in adult patients with coronary artery disease or symptomatic peripheral artery disease at high risk of ischaemic events.

<https://www.medicines.org.uk/emc/product/3410/smpc>

Xydol (tramadol) XL tablets (all strengths)

SPCs have been updated with text on: dependence /treatment discontinuation; use in post-operative /respiratory compromised children; inhibition of one or both types of isoenzymes CYP3A4 and CYP2D6 affecting plasma levels of tramadol. Breast-feeding section has been updated.

<https://www.medicines.org.uk/emc/product/86/smpc>