Medicines Safety Assurance Tool

March 2018

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

MIDLANDS AND LANCASHIRE COMMISSIONING SUPPORT UNIT

Esmya (ulpristal acetate) for uterine fibroids: do not initiate or re-start treatment; monitor liver function in current and recent users

MHRA | 09 Mar 2018

The March edition of the Drug Safety Update newsletter discusses temporary safety measures introduced to protect women's health whilst a safety review of this product is ongoing. The EU-wide review was initiated in December 2017 following reports of serious liver injury.

https://www.gov.uk/drug-safety-update/esmya-ulipristal-acetate-for-uterine-fibroids-do-not-initiate-or-re-start-treatment-monitor-liver-function-in-current-and-recent-users

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Head lice eradication products: risk of serious burns if treated hair is exposed to open flames or other sources of ignition, e.g. cigarettes

MHRA | 09 Mar 2018

The March edition of Drug Safety Update highlights the risk of fires with these products. Despite the addition of warnings to the pack and patient information for Hedrin 4% cutaneous solution, there have since been two further cases of serious burns associated with other products.

https://www.gov.uk/drug-safety-update/head-lice-eradication-products

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Updated Measures for pregnancy prevention during retinoid use

European Medicines Agency | 23 Mar 2018

The EMA has completed a review of available data on teratogenicity and neuropsychiatric disorders with retinoid medicines and concluded that there is the need to strengthen the recommendations for pregnancy prevention and to raise awareness about possible neuropsychiatric risks.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Retinoids_

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Colour change for Fiasp (Insulin aspart) to avoid mix-ups with Tresiba (insulin degludec)

European Medicines Agency | 23 Mar 2018

The colour of Fiasp cartridges, pre-filled pens and vials is changing from yellow to red and yellow, following cases where patients have mistakenly injected it instead of Tresiba (available in the EU as light green cartridges and pens) or the other way around.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/03/news_detail_002931.jsp&mid=WC0b01ac058004d5c1

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

New measures to avoid valproate exposure in pregnancy

European Medicines Agency | 26 Mar 2018

Valproate is now contraindicated for migraine or bipolar disorder during pregnancy, for treating epilepsy during pregnancy unless there are no alternatives and, in any woman, / girl able to have children unless conditions of a new pregnancy prevention programme are met.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/03/news_detail_002929.jsp&mid=WC0b01ac058004d5c1

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 | Mar 2018

Actrapid (Insulin. Human) 100 international units/ml, Solution for injection in a vial

The statement "in case of emergency in current Actrapid users (hospitalisation or insulin pen malfunction), Actrapid can be withdrawn with an U100 insulin syringe from a cartridge or pre-filled pen" has been removed from SPC.

https://www.medicines.org.uk/emc/product/3849/smpc

AirFluSal MDI 25 microgram/125microgram(salmeterol/fluticasone) per actuation pressurised inhalation, suspension

Blurred vision has been added as an undesirable effect (frequency not known). Visual disturbance may be reported with systemic and topical corticosteroid use. Affected patients should be considered for referral to ophthalmologist for evaluation of possible causes.

https://www.medicines.org.uk/emc/product/8786/smpc

Augmentin (amoxicillin/clavulanic acid) products

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been added to SPC as a new adverse effect (frequency unknown).

https://www.medicines.org.uk/emc/product/280/smpc

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

APO-go (apomorphine hydrochloride) pen, prefilled syringe and ampoules
Based on post-marketing pharmacovigilance data, headache has now been included as an adverse reaction.
https://www.medicines.org.uk/emc/product/2232/smpc

Cobalin-H (hydroxocobalamin) injection
The SPC advises to confirm the diagnosis of Vitamin B12 deficiency before administering hydroxocobalamin and notes that although it is secreted into breast milk it is unlikely to harm the infant. Further information on vitamin B12 deficiency is also outlined.
https://www.medicines.org.uk/emc/product/4662/smpc

Depakote (semisodium valproate) Tablets
Section 4.4 now advises patients with an underlying carnitine palmitoyl transferase type II deficiency should be warned of the greater risk of rhabdomyolysis when taking semisodium valproate. Section 4.5 also lists new drug-drug interactions.
https://www.medicines.org.uk/emc/product/6102/smpc

Diovan (valsartan) Oral Solution
Section 4.5 now notes that reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin II receptor antagonists (previously only ACE inhibitors).
https://www.medicines.org.uk/emc/product/5991/smpc

Efexor (venlafaxine) capsules – all strengths
Venlafaxine should be used with caution in patients with MI or unstable heart disease. Post-marketing cases of QTc prolongation, Torsade de Pointes, ventricular tachycardia, and fatal cardiac arrhythmias have been reported especially in overdose or in patients with risk factors.
https://www.medicines.org.uk/emc/product/5059/smpc

Epilim (sodium valproate) – Strengths and presentations
Section 4.4 now advises patients with an underlying carnitine palmitoyl transferase type II deficiency should be warned of the greater risk of rhabdomyolysis when taking semisodium valproate. Section 4.5 also lists new drug-drug interactions.
https://www.medicines.org.uk/emc/product/519/smpc

Equasym (methylphenidate) XL Capsule (all strengths)
Erectile dysfunction and logorrhoea (excessive, uncontrollable, or incoherent talkativeness) have been added to SPC as adverse effects.
https://www.medicines.org.uk/emc/product/7456/smpc

Flixonase (fluticasone propionate) Nasule Drops

Flixonase (fluticasone propionate) Nasule Drops

Visual disturbance and blurred vision have been added as potential adverse effects from treatment (frequency). Nasal ulcers have now been listed as an adverse reaction in section 4.8.

https://www.medicines.org.uk/emc/product/5503/smpc

Lodotra (prednisolone) tablets

SPC has been updated to advise caution when used in patients with systemic sclerosis because of an increased incidence of (possibly fatal) scleroderma renal crisis with hypertension and decreased urinary output seen with daily dose of ≥15 mg prednisolone.

https://www.medicines.org.uk/emc/product/7650/smpc

MST Continus (morphine) suspension – all strengths

SPC warns that concomitant use of benzodiazepines and opioids only advised when alternative treatment options are not possible. It is also noted that opioids may influence the hypothalamic-pituitary-adrenal or –gonadal axes resulting in hormonal changes and clinical symptoms.

https://www.medicines.org.uk/emc/product/7658

Omacor (Omega-3-acid ethyl esters)

SPC now highlights that Omacor contains soya oil, and those with an allergy to soya or peanuts should not take this product.

https://www.medicines.org.uk/emc/product/1706/smpc

Orap (pimozide) 4mg tablets

Orap is now licensed for the treatment of chronic schizophrenia and other psychoses in children over 12 years old.

https://www.medicines.org.uk/emc/product/6911

Orkambi Film-coated Tablets

Increased blood creatine phosphokinase has been added as a common adverse event. The shelf life has also increased from 2 to 4 years.

https://www.medicines.org.uk/emc/product/8952/smpc

Pentasa (mesalazine) products

Following PRAC recommendation, photosensitivity has been added to SPC as a rare adverse event.

https://www.medicines.org.uk/emc/product/4778/smpc

Phyllocontin Continus and Forte Continus (aminophylline)
Use of aminophylline and ephedrine in children < 6 years (or < 22 kg) and monotherapy in children <6 months is contraindicated. Theophylline clearance is increased by isoprenaline, ritonavir and St John's Wort. Theophylline also interacts with ciprofloxacin and enoxacin.
https://www.medicines.org.uk/emc/product/1019

Ravicti (glycerol phenylbutyrate) 1.1g/ml oral liquid
The expiry of the bottle once opened has been changed from 3 days to 14 days. The resealable bottle cap should be discarded when the bottle is empty or after 3 14 days following opening even if the bottle is not empty.
https://www.medicines.org.uk/emc/product/2494

Revlar Ellipta 92micrograms/22micrograms inhalation powder, pre-dispensed
This product is now also licensed for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of long-acting beta2-agonist and inhaled corticosteroid is appropriate.
https://www.medicines.org.uk/emc/product/5225/smpc

Rivastigmine patch (Exelon/Prometax): Instructions for use and patient diary for patients
These instructions are to be provided to patients to ensure correct use of rivastigmine patches. The information also includes a medication record sheet aimed at informing the day/date of removal of the old patch and application of the new patch.
https://www.medicines.org.uk/emc/rmm/1146/Document

Sandostatin (octreotide) -all formulations and strengths
For acromegaly, a maximum dose of 1.5 mg per day should not be exceeded. For patients on a stable dose, assessment of GH and IGF-1 should be made every 6 months. Further information on cholelithiasis has been added.
https://www.medicines.org.uk/emc/product/7825

Sporanox (itraconazole) oral solution
SPC advises caution with co-administration of telapravir and itraconazole due to increased exposure to itraconazole. Patients should be monitored and itraconazole dose be reduced if necessary. If appropriate, itraconazole plasma concentrations can also be measured.
https://www.medicines.org.uk/emc/product/1522/smpc

Tamiflu (oseltamivir) – all formulations

The information on the use of oseltamivir in pregnancy has been updated. Use in pregnancy requires consideration of the available safety and benefit and the pathogenicity of the circulating influenza virus strain.

https://www.medicines.org.uk/emc/product/1194/smpc

Trulicity (dulaglutide) solution for injection in pre-filled syringe – all strengths

The SPC advises no dosage adjustment is required in patients with mild, moderate or severe renal impairment (eGFR <90 to ≥15mL/min/1.73 m2). However, due to limited experience of dulaglutide in end-stage renal disease (<15mL/min/1.73m2) it cannot be recommended in this population. Non-mechanical intestinal obstruction has been added as a potential adverse effect of treatment – frequency unknown

https://www.medicines.org.uk/emc/product/8246/smpc

Viekirax 12.5/75mg/50 (ombitasvir, paritaprevir and rotinavir) film-coated tablets

Disopyramide has now been added to the list of medicines that cannot be co-administered in patients on Viekerax. Anaphylactic reactions have been added as an adverse effect.

https://www.medicines.org.uk/emc/product/3644/smpc

Xeplion (paliperidone palmitate) prolonged-release suspension for injection (all strengths)

The SPC now features a dosage conversion table to provide guidance for healthcare professionals when switching patients from paliperidone tablets to paliperidone palmitate long-acting injection.

https://www.medicines.org.uk/emc/product/9053/smpc

Zyban (bupropion) 150mg prolonged release tablets

Urinary incontinence has been added to SPC as an adverse effect (very rare frequency).

https://www.medicines.org.uk/emc/product/3827/smpc

statusOptions
Unassigned
Red
Amber
Green