Medicines Safety Assurance Tool

September 2017

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

Error with the barcodes on selected batches of 8 medicinal products

Central Alerting System | 04 Sep 2017

Focus Pharmaceuticals has identified an error with the barcodes on the cartons of the listed batches of products. When scanned, the barcodes may identify the wrong product. The other product details on the carton, including the name, strength and pharmaceutical form of the medicine are correct.
https://www.gov.uk/drug-device-alerts/error-with-the-barcodes-on-selected-batches-of-8-medicinal-products-by-focus-pharmaceuticals-distribute-to-pharmacy-and-wholesaler-level

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Guidance for the Correct Use and Disposal of Batteries Used in Health and Social Care Equipment

Central Alerting System | 06 Sep 2017

The use and incorrect disposal of batteries may result in equipment/devices emitting smoke and fumes, not functioning normally, quickly running out of power, being permanently damaged and, in certain circumstances, there may be a fire.
https://www.cas.dh.gov.uk/ViewAndAcknowledgment/viewAttachment.aspx?Attachment_id=102843

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

All Accu-Chek® Insight insulin pumps - risk of alarm failure

Central Alerting System | 21 Sep 2017

Manufactured by Roche Diabetes Care – the audible and/or vibration alarms might not function, which may lead to hyperglycaemia if the user doesn't see the notification message on the pump.

https://www.cas.dh.gov.uk/ViewAndAcknowledgment/viewAttachment.aspx?Attachment_id=102845

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Miconazole (Daktarin): over-the-counter oral gel contraindicated in patients taking warfarin

MHRA Drug Safety Update | 26 Sep 2017

Patients taking warfarin should not use over-the-counter miconazole oral gel (Daktarin). If you plan to prescribe miconazole oral gel in a patient on warfarin, you should closely monitor them and advise that if they experience any sign of bleeding, they should stop miconazole oral gel and seek immediate medical attention.

https://www.gov.uk/drug-safety-update/miconazole-daktarin-over-the-counter-oral-gel-contraindicated-in-patients-taking-warfarin

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Loperamide (Imodium): reports of serious cardiac adverse reactions with high doses of loperamide associated with abuse or misuse

MHRA Drug Safety Update | 26 Sep 2017

There have been reports of cardiac events including QT prolongation, torsades de pointes, and cardiac arrest in patients who have taken high or very high doses of loperamide as a drug of abuse or for self-treatment of opioid withdrawal.
https://www.gov.uk/drug-safety-update/loperamide-imodium-reports-of-serious-cardiac-adverse-reactions-with-high-doses-of-loperamide-associated-with-abuse-or-misuse

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Xarelto 20 mg film-coated tablets - CLASS 2 MEDICINES RECALL

Central Alerting System | 28 Sep 2017

Strathclyde Pharmaceuticals Ltd has received a report of a rogue blister strip of 15 mg tablets within two packs of 20 mg tablets and has decided to recall this batch.
https://www.cas.dh.gov.uk/ViewAndAcknowledgment/viewAttachment.aspx?Attachment_id=102848

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

What is the risk of interaction between opioids and monoamine oxidase inhibitors (MAOIs)?

South West Medicines Information and Training | 27th September 2017

This article considers the risks of interaction between opioids and monoamine oxidase inhibitors.

https://www.sps.nhs.uk/articles/what-is-the-risk-of-interaction-between-opioids-and-monoamine-oxidase-inhibitors-maois/

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

electronic Medicines Compendium | Sep 2017

Aranesp (darbepoetin) – all formulations

Severe cutaneous adverse reactions (frequency not known) including Stevens-Johnson syndrome and toxic epidermal necrolysis, which can be life-threatening or fatal, have been reported in association with epoetin treatment. Treatment should be withdrawn immediately.

http://www.medicines.org.uk/emc/medicine/30617

Calcichew (calcium carbonate) 500mg Chewable Tablets

The SPC has been updated to remove aspartame and sorbitol from the list of excipients, and to remove the warning that it should be avoided by patients with phenylketonuria. Xylitol and sucralose are included as new excipients.

http://www.medicines.org.uk/emc/medicine/28505

Calcichew-D3 Forte Chewable Tablets

Sorbitol and aspartame have been removed from the list of excipients. The warning that Calchichew D3 Forte may be harmful to people with phenylketonuria has been removed (aspartame is a source of phenylalanine)

http://www.medicines.org.uk/emc/medicine/28502

Decapeptyl SR 22.5mg (triptorelin pamoate)

A number of sections have been updated due to the addition of a new indication for central precocious puberty.

http://www.medicines.org.uk/emc/medicine/24154

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Dianette (cyproterone acetate; ethinylestradiol)
Concomitant use with medicines containing ombitasvir/paritaprevir/ritonavir or dasabuvir is now contra-indicated as this may increase the risk of transaminase (ALT) elevations (seen more frequently in women using ethinylestradiol-containing medications in clinical trials).
http://www.medicines.org.uk/emc/medicine/1814

Dymista (fluticasone propionate/azelastine hydrochloride) nasal spray
Section 4.4 now advises that visual disturbance may be reported with systemic and topical corticosteroid use (symptoms include blurred vision or other visual disturbances; possible causes include cataract, glaucoma or rare diseases such as central serous chorioretinopathy.
http://www.medicines.org.uk/emc/medicine/27579

Entocort (budesonide) CR 3mg Capsules
Entocort CR capsules are now licensed for the treatment of active microscopic colitis. The recommended dose is 9 mg once daily in the morning (corresponding to 3 capsules).
http://www.medicines.org.uk/emc/medicine/172

Epanutin (phenytoin) preparations
Section 4.8 has been updated to include “thyroid function test abnormal” as an adverse drug reaction.
http://www.medicines.org.uk/emc/medicine/13289

Eperzan (albiglutide) 30 mg and 50 mg powder and solvent for solution for injection
Angioedema, as an adverse allergic reaction, is now listed in section 4.8.
http://www.medicines.org.uk/emc/medicine/31399

Epilim (sodium valproate) and Depakote (valproate semisodium) preparations
In patients concomitantly treated with sodium valproate and nimodipine, the exposure to nimodipine can be increased by 50%. The nimodipine dose should, therefore, be decreased in case of hypotension.
http://www.medicines.org.uk/emc/medicine/25929

EpiPen Adrenaline (Epinephrine) Auto-Injectors
Various changes have been made to the SPC. This includes the addition of the following statement: “rare cases of serious skin and soft tissue infections, including necrotizing fasciitis and myonecrosis caused by Clostridia (gas gangrene) are known from post-marketing experience”.
http://www.medicines.org.uk/emc/medicine/26974

Exjade (deferasirox) film-coated tablets
Drug reaction with eosinophilia and systemic symptoms (DRESS) has been added as a rare adverse effect of treatment. If any severe cutaneous adverse reaction is suspected deferasirox should be discontinued immediately and not reintroduced.
http://www.medicines.org.uk/emc/medicine/32428

Famvir (famciclovir) tablets (all strengths)
The following adverse effects have been added: seizure (frequency not known), anaphylactic shock and anaphylactic reaction (frequency not known).
http://www.medicines.org.uk/emc/medicine/6651

Faverin (fluvoxamine) 100 mg film-coated tablets
Owing to fluvoxamine being a CYP2C19 inhibitor, the SPC now advises that concomitant use of fluvoxamine and clopidogrel is discouraged. Clopidogrel is metabolised to its active form by CYP2C19.
http://www.medicines.org.uk/emc/medicine/22124

Fultium-D3 (colecalciferol; cholecalciferol) 3,200IU capsules
SPC has been updated to reflect licence extension for the treatment of vitamin D deficiency in adolescents and also to advise that Fultium-D3 should not be used in children under the age of 12.
http://www.medicines.org.uk/emc/medicine/28806

Humira (adalimumab) preparations
Various sections of the SPC have been updated to reflect the approval of its use in the treatment of paediatric uveitis.
http://www.medicines.org.uk/emc/medicine/31860

IntronA (interferon alfa-2b) preparations
SPC warns that cases of hepatitis B re-activation have been reported in patients co-infected with hepatitis B and C viruses treated with interferon, and advises that all patients be screened for hepatitis B before starting treatment. Pericarditis has been added as a side-effect.
http://www.medicines.org.uk/emc/medicine/20382

Invega (paliperidone) 3 mg, 6mg, 9 mg and 12mg prolonged-release tablets
The recommended initial dose in moderate to severe renal impairment (CrCl 10-50ml/min) is now 3mg every other day (previously recommended 1.5mg every other day as the initial dose in these patients). The dose may be increased to 3mg once daily after clinical assessment.
http://www.medicines.org.uk/emc/medicine/30349

Kaletra (100mg lopinavir /25mg ritonavir) film-coated tablets
New contraindications and interaction information with venetoclax, with elbasvir/grazoprevir and with ombitasvir/paritaprevir/ritonavir with or without dasabuvir have been added to SPC.
http://www.medicines.org.uk/emc/medicine/20855

Ketoconazole HRA 200mg Tablets
Drug interactions with edoxaban and isavuconazole have been added. Ketoconazole significantly increased the AUC of isavuconazole, and concomitant use is not recommended. Dose reductions of edoxaban are recommended with concomitant use (refer to edoxaban SPC).
http://www.medicines.org.uk/emc/medicine/30077

Mekinist (trametinib) film-coated tablets
Photosensitivity has been added as a common adverse effect of treatment.
http://www.medicines.org.uk/emc/medicine/31241

Mavenclad (cladribine) 10mg tablets: Prescribers guide and patients' guide
The prescribers guide provides information on the most important risks associated with MAVENCLAD® and monitoring required to minimise these risks.
http://www.medicines.org.uk/emc/RMM.1034.pdf

Neurontin (gabapentin) preparations
SPC now advises that gabapentin has been associated with severe respiratory depression. Patients with respiratory disease, renal impairment, concomitant use of CNS depressants and the elderly might be at higher risk and dose adjustments might be necessary for these patients.
http://www.medicines.org.uk/emc/medicine/27900

Norvir (ritonavir) products
Contraindication regarding the interaction between ritonavir and venetoclax has been added to SPC.
http://www.medicines.org.uk/emc/medicine/22952

Orkambi (lumacaftor and ivacaftor) 200 mg/125 mg film-coated tablets
SPC has been updated to note serious respiratory events were seen more frequently in patients with percent predicted FEV1 <40, to describe the risk of potential fatal decompensation in patients with cirrhosis and portal hypertension, and to add cataracts as a side-effect.
http://www.medicines.org.uk/emc/medicine/31534

Prolia (denosumab)
Cataracts as an adverse drug reaction of denosumab has been removed from the SPC.
http://www.medicines.org.uk/emc/medicine/23127

Proscar (finasteride) 5mg film-coated Tablets
SPC now warns that cases of depression, mood alterations and suicidal ideation have been reported.
http://www.medicines.org.uk/emc/medicine/1190

Reyataz (atazanavir) Capsules
Sections 4.4 and 4.8 have been updated with post-marketing reports of chronic kidney disease (frequency uncommon). Regular monitoring of renal function is advised throughout the treatment duration.
http://www.medicines.org.uk/emc/medicine/14145

Siklos (hydroxycarbamide) 1000mg Film-Coated Tablets
Educational materials for physicians contain important information on minimising the risk of serious adverse events and monitoring requirements. A booklet for patients contains safety information that they need to be aware of before, during and after treatment with Siklos.
http://www.medicines.org.uk/emc/medicine/26268#rmm

Sovaldi (sofosbuvir) 400 mg film-coated tablets
SPC has been updated with an extension of indication to include treatment of chronic hepatitis C in adolescents aged 12 to < 18 years.
http://www.medicines.org.uk/emc/medicine/28539

Stivarga (regorafenib) 40 mg film-coated tablets
Regorafenib is now licensed for the treatment of adults with hepatocellular carcinoma who have been previously treated with sorafenib. Changes relating to this new indication have been made throughout the SPC.
http://www.medicines.org.uk/emc/medicine/28270

Tafinlar (dabrafenib) 50 mg & 75 mg hard capsules
Data from an interaction study with rabeprazole has been added; the SPC now notes that medicines that alter the pH of the upper gastrointestinal tract are not expected to reduce the bioavailability of dabrafenib. Data from an interaction study with rifampin has also been added.
http://www.medicines.org.uk/emc/medicine/28432

Tobradex (tobramycin and dexamethasone) Eye Drops
Additions include anaphylactic reaction and erythema multiforme (adverse effects); untreated parasitic eye infections (contraindication); and a paragraph on interaction with inhibitors of CYP3A4. Sections on pregnancy and breastfeeding have been completely updated.
http://www.medicines.org.uk/emc/medicine/4670

Topamax (topiramate) all strengths
Section 4.4 now advises the risk for hyperammonemia with topiramate appears dose-related and has been reported more frequently when topiramate is used concomitantly with valproic acid and provides advice on management. Sections 4.5 and 4.8 have also been updated accordingly.
http://www.medicines.org.uk/emc/medicine/31483

Vargatef (nintedanib) 100 mg and 150 mg soft capsules
Information regarding post-marketing cases of diarrhoea (serious) and bleeding (serious and non-serious) has been added, as has information regarding the possible requirement for interruption, dose reduction and discontinuation of therapy in an event of dehydration.
http://www.medicines.org.uk/emc/medicine/29790

Varilrix (live attenuated varicella-zoster virus - Oka strain) vaccine
Varilrix is now licensed for active immunisation against varicella of healthy subjects from the age of 9 months. Other sections have been revised to reflect this indication. Additionally, information about interchangeability with other varicella-containing vaccines has been added
http://www.medicines.org.uk/emc/medicine/9787