Medicines Safety Assurance Tool

January 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

In use product safety assessment report for methotrexate pre-filled devices

UKMi | 22 Nov 2017

This UKMi Product Safety assessment on methotrexate pre-filled devices identifies relevant differences between these products and highlights any potential safety concerns in case of intentional or unintentional switching between them.
https://www.sps.nhs.uk/wp-content/uploads/2017/11/Methotrexate_SC_products_Nov17_final.doc

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

How should conversion from oral morphine to fentanyl patches be carried out?

UKMi | 19 Dec 2017

This updated Medicines Q&A considers the factors which need to be considered when converting patients from oral morphine to fentanyl patches.
https://www.sps.nhs.uk/wp-content/uploads/2017/12/UKMI_QA_Conversion-from-oral-morphine-to-fentanyl-patches_November-2017_Final.docx

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

What is the first choice antidepressant for patients with renal impairment?

UKMi | 05 Jan 2018

This updated Medicines Q&A evaluates the limited published evidence available on the use of antidepressants in patients with renal impairment.

https://www.sps.nhs.uk/wp-content/uploads/2018/01/QA_Antidepress_RI_2018_final.docx

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Risk of death and severe harm from failure to obtain and continue flow from oxygen cylinders

Central Alerting System | 09 Jan 2018

This alert asks all organisations to adopt a systematic approach to ensuring all their staff using oxygen cylinders can safely operate them.

https://www.cas.dh.gov.uk/ViewAndAcknowledgment/viewAttachment.aspx?Attachment_id=102915

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Drug-name confusion: reminder to be vigilant for potential errors

Medicines and Healthcare products Regulatory Agency | 09 Jan 2018

Take particular care when prescribing or dispensing medicines that could be confused with others (ie, they sound-alike or look-alike).

https://www.gov.uk/drug-safety-update/drug-name-confusion-reminder-to-be-vigilant-for-potential-errors

Proposed action

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

Action taken

Status: Unassigned

Action due date

Date completed

Co-dydramol: prescribe and dispense by strength to minimise risk of medication error

Medicines and Healthcare products Regulatory Agency | 09 Jan 2018

Previously co-dydramol (dihydrocodeine/paracetamol) was available only in the ratio 1:50 (co-dydramol 10/500 mg). Two products are now available with a higher strength of dihydrocodeine (co-dydramol 20/500 mg and 30/500 mg tablets). It is therefore important that co-dydramol products are prescribed and dispensed by strength to minimise dispensing errors and the risk of accidental opioid overdose.

https://www.gov.uk/drug-safety-update/co-dydramol-prescribe-and-dispense-by-strength-to-minimise-risk-of-medication-error

Proposed action

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

Action taken

Status: Unassigned

Action due date

Date completed

Herbal medicines: report suspected adverse reactions to the Yellow Card Scheme

Medicines and Healthcare products Regulatory Agency | 09 Jan 2018

If an adverse reaction is suspected, ask patients whether they are taking any herbal medicines and discuss with them the importance of reporting this via the Yellow Card Scheme.

https://www.gov.uk/drug-safety-update/herbal-medicines-report-suspected-adverse-reactions-to-the-yellow-card-scheme

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

In use product safety assessment report: Onexila® XL (oxycodone once daily prolonged release tablets)

Specialist Pharmacy Services | 31 Jan 2018

This review summarises practical in-use safety considerations for the introduction of Onexila XL. This is the first modified release(MR) oxycodone product in the UK market that has a once daily dosing regimen; all other MR preparations of oxycodone are twice daily dosing regimens

https://www.sps.nhs.uk/articles/in-use-product-safety-assessment-report-onexila-xl-oxycodone-once-daily-prolonged-release-tablets/

Proposed action

- [x] 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 | Jan 2018

Amoxil (amoxicillin) capsules

Drug Reaction with eosinophilia and systemic symptoms (DRESS) syndrome has been added as a potential adverse effect of treatment (frequency – very rare).

https://www.medicines.org.uk/emc/product/91/smpc

Boostrix-IPV suspension for injection (diphtheria, tetanus, pertussis and poliomyelitis)

The SPC notes that there is no increased reactogenicity after the second dose compared to the first one in subjects aged 15 years onwards without recent vaccination for diphtheria, tetanus, pertussis and poliomyelitis.

https://www.medicines.org.uk/emc/product/5302/smpc

Celecoxib capsules

SPC now clarifies that the increase in risk for cardiovascular thromboembolic events associated with non-aspirin NSAIDs use occurs irrespective of the presence of underlying cardiovascular disease (CVD) or CV risk factors.

https://www.medicines.org.uk/emc/product/3423/smpc

CellCept (mycophenolate mofetil) 1g/5ml powder for oral suspension

SPC now recommends that disposable gloves should be worn during reconstitution and when wiping the outer surface of the bottle/cap and the table after reconstitution.

https://www.medicines.org.uk/emc/product/1569/smpc

Diamox (acetazolamide) SR 250mg Capsules and 500mg Powder for Solution for Injection

Sections 4.4 and 4.8 have been updated to advise of the occurrence at treatment initiation, of feverish generalized erythema associated with pustula which may be a symptom of acute generalised exanthematous pustulosis (AGEP) – if AGEP is diagnosed, treatment must be discontinued.

https://www.medicines.org.uk/emc/product/5669/smpc

Fluarix Tetra - Influenza vaccine (split virion, inactivated)

Fluarix Tetra is now licensed for active immunisation for infants >6months for prevention of influenza disease caused by the two influenza A and two influenza B virus types. Section 4.5 has also been updated to include information on co-administration with pneumococcal vaccine.

https://www.medicines.org.uk/emc/product/3021/smpc

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Gilenya (fingolimod) 0.5mg hard capsules
The SPC has been updated to include contra-indications to the use of fingolimod in patients with cardiac arrhythmias, and patients with a history of MI, unstable angina, stroke/TIA, decompensated heart failure, or NYHA class III/IV heart failure in the previous 6 months.
https://www.medicines.org.uk/emc/product/4545/smpc

Istin (amlodipine) 5 and 10mg tablets
Section 4.5 has been reworded to state that amlodipine is a weak CYP3A inhibitor, and concomitant use with mTOR inhibitors (sirolimus, temsirolimus, everolimus), which are CYP3A substrates, may increase their drug levels. Wording regarding co-administration with strong CYP3A4 inducers has been revised, as has the breast-feeding section, which now notes the estimated proportion of the maternal dose received by the infant during lactation (interquartile range 3-7%; maximum 15%).
https://www.medicines.org.uk/emc/product/2925/smpc

Mydrilate (cyclopentolate) Eye Drops – all strengths
Section 4.8 has been updated to include convulsions and partial seizures in children as potential adverse reactions.
https://www.medicines.org.uk/emc/product/1724/smpc

Nuvaring (ethinylestradiol, etonogestrel)
Instruction to use NuvaRing with other female vaginal barrier methods have been added to SPC, as has vaginal ring site tissue overgrowth as an adverse reaction (frequency unknown), and related text on removal of NuvaRing should this problem arise.
https://www.medicines.org.uk/emc/product/6449/smpc

Palexia (tapentadol) SR prolonged release tablets
The SPC has been updated to include the fact that the shell of the tablet may not be digested completely and maybe present in faeces, but that this has no clinical relevance.
https://www.medicines.org.uk/emc/product/5158/smpc

Plavix (clopidogrel) tablets
Ageusia has been added as a very rare potential adverse effect of treatment
https://www.medicines.org.uk/emc/product/5934/smpc

Quadrivalent Influenza vaccine (Split virion, inactivated)
The therapeutic indication for active immunisation of adults and children has been extended to age from 6 months and above (previously from age 3 years and older).
https://www.medicines.org.uk/emc/product/666/smpc

Salofalk (mesalazine) – all formulations
Photosensitivity has been added as an adverse effect.
https://www.medicines.org.uk/emc/product/140/smpc

Samsca (tolvaptan) 7.5 mg, 15mg and 30mg tablets
A 7.5mg strength has been introduced. For patients at risk of overly rapid correction of sodium e.g. patients with oncological conditions, very low baseline serum sodium, taking diuretics, or taking sodium supplementation a dose of 7.5mg should be considered.
https://www.medicines.org.uk/emc/product/8848

Tegretol (carbamazepine) – all formulations
Section 4.5 now advises concomitant use of carbamazepine with direct acting oral anti-coagulants (DOACs: rivaroxaban, dabigatran, apixaban and edoxaban) may lead to reduced plasma concentrations of DOACs, which carries the risk of thrombosis. Closer monitoring is recommended.
https://www.medicines.org.uk/emc/product/1041/smpc

Tildiem (diltiazem) – all formulations
Section 4.5 now advises that diltiazem has been shown to inhibit platelet aggregation. Although the clinical significance is unknown, potential additive effects when used with antiplatelet drugs should be considered. Diltiazem has been shown to increase cilostazol exposure.
https://www.medicines.org.uk/emc/product/4971/smpc

Trumenba (meningococcal group B vaccine; recombinant, adsorbed)
SPC now states syncope can occur in association with administration of Trumenba and procedures should be in place to avoid injury from fainting. It also highlights lack of data on interchangeability with other meningococcal group B vaccines to complete vaccination series.
https://www.medicines.org.uk/emc/product/2670/smpc

Zirtek (cetirizine) Allergy 10 mg film-coated Tablets
Nightmare, acute generalized exanthematous pustulosis and arthralgia have been added as new potential adverse effects of treatment (frequency unknown for all)
https://www.medicines.org.uk/emc/product/6751/smpc

Zonegran (zonisamide) hard capsules – all strengths
Sections 4.4 and 4.6 have been updated to advise that zonisamide must not be used in women of childbearing potential not using effective contraception unless clearly necessary and only if the potential benefit is considered to justify the risk to the foetus.
https://www.medicines.org.uk/emc/product/7871/smpc

Zostavax (varicella-zoster virus [live])
Section 4.4 has been updated to complement the safety information regarding the vaccination of immunosuppressed or immunodeficient patients, which may result in disseminated varicella-zoster virus disease, including fatal outcomes.
https://www.medicines.org.uk/emc/product/6101/smpc

Zyloric (allopurinol) Tablets 100mg
SPC now advises that screening for HLA-B*5801 should be considered before starting treatment with allopurinol in patient subgroups where the prevalence of this allele is known to be high (e.g. Han Chinese, Thai and Korean)
https://www.medicines.org.uk/emc/product/1312/smpc