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Medicines Safety Assurance Tool

December 2018

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Midlands and Lancashire
Commissioning Support Unit

In use product safety assessment report for enoxaparin biosimilars (INHIXA and AROVI)

Specialist Pharmacy Service | 12 December 2018

This assessment on Inhixa and Arovi (enoxaparin biosimilars) describes the in-use medication safety considerations resultant from the products' presentation or other pre-defined characteristics. Potential next steps and mitigation actions are suggested. <https://www.sps.nhs.uk/articles/in-use-product-safety-assessment-report-for-inhixa-enoxaparin-biosimilar/>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Emollients: new information about risk of severe and fatal burns with paraffin-containing and paraffin-free emollients

Medicines and Healthcare products Regulatory Agency | 18 December 2018

Warnings about risk of severe and fatal burns are being extended to all paraffin-based emollients regardless of paraffin concentration. Data suggest there is also a risk for paraffin-free emollients. Patients who use these products are advised not to smoke/go near naked flames.

<https://www.gov.uk/drug-safety-update/emollients-new-information-about-risk-of-severe-and-fatal-burns-with-paraffin-containing-and-paraffin-free-emollients>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Hydrocortisone muco-adhesive buccal tablets: should not be used off-label for adrenal insufficiency in children due to serious risks

Medicines and Healthcare products Regulatory Agency | 18 December 2018

Alert reiterates hydrocortisone muco-adhesive buccal tablets are indicated only for local use in the mouth for aphthous ulceration; and if incorrectly used for treating adrenal insufficiency, there is risk of insufficient cortisol absorption and life-threatening adrenal crisis.

<https://www.gov.uk/drug-safety-update/hydrocortisone-muco-adhesive-buccal-tablets-should-not-be-used-off-label-for-adrenal-insufficiency-in-children-due-to-serious-risks>

Proposed action

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



[Redacted area]

Action taken

[Redacted area]

Status	Action due date	Date completed
Unassigned ▼	[Redacted]	[Redacted]

Valproate medicines: are you in acting in compliance with the pregnancy prevention measures?

Medicines and Healthcare products Regulatory Agency | 18 December 2018

The MHRA has noted there is wide variation in prescribing between CCGs and women continue to report instances when they have not received patient information with their dispensed valproate (VP) medicine. All healthcare professionals must continue to identify/review all female patients on VP.

<https://www.gov.uk/drug-safety-update/valproate-medicines-are-you-in-acting-in-compliance-with-the-pregnancy-prevention-measures>

Proposed action

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



[Redacted area]

Action taken

[Redacted area]

Status	Action due date	Date completed
Unassigned ▼	[Redacted]	[Redacted]

Herbal skin cream found to contain steroids

Medicines and Healthcare products Regulatory Agency | 19 December 2018

The MHRA advises that a skin cream claiming to be a natural Chinese herbal remedy for treating eczema (Zudaifu), contains a potentially harmful steroid (clobetasol) and should not be used.

<https://www.gov.uk/government/news/herbal-skin-cream-found-to-contain-steroids>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

What information is available on drugs in diving?

Specialist Pharmacy Service | 21 December 2018

This Q & A highlights that professional divers are required by law to undergo a medical assessment by a clinician trained in diving medicines; and the underlying condition for which medications are being taken will be one of the most important considerations.

<https://www.sps.nhs.uk/articles/what-information-is-available-on-drugs-in-diving/>

Proposed action

- 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?

Specialist Pharmacy Service | 21 December 2018

This Q & A states the majority of antidepressants can be used in renal impairment with caution; however side effects may be enhanced and extra caution may be needed when switching between antidepressants as half-lives may be extended.

<https://www.sps.nhs.uk/articles/what-is-the-first-choice-antidepressant-for-patients-with-renal-impairment/>

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)?

Specialist Pharmacy Service | 21 December 2018

This Q & A states given widespread availability of suitable alternative drugs, the combination of dextromethorphan, methadone, tramadol, fentanyl or tapentadol with an MAOI should be avoided, including in the 14 day period following the withdrawal of an irreversible MAOI.

<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

Which opioids can be used in renal impairment?

Specialist Pharmacy Service | 21 December 2018

This Q & A states renal impairment not only alters the clearance of the parent compound but also affects the accumulation of its metabolites; elimination may also be prolonged. Recommendations for adjustment of doses are based on pharmacokinetic studies and clinical experience.

<https://www.sps.nhs.uk/articles/which-opioids-can-be-used-in-renal-impairment/>


Proposed action 

Newsletter Optimise Rx/ScriptSwitch

Practice audit/search Other (please specify)

Action taken

Status Action due date Date completed

Unassigned  _____

Summary of Product Characteristics Update

Electronic Medicines Compendium | December 2018

Bexsero Meningococcal Group B vaccine for injection in pre-filled syringe

The SPC now includes meningeal irritation as an adverse drug event (frequency not known).

<https://www.medicines.org.uk/emc/product/5168/smpc>

Bricanyl Turbohaler, 0.5mg/dose, inhalation powder

The SPC notes that this inhaler contains lactose monohydrate (<1 mg/inhalation) which does not normally cause problems in lactose intolerant people. However, lactose may contain small amounts of milk protein residues which may cause allergic reactions in hypersensitive patients.

<https://www.medicines.org.uk/emc/product/869/smpc>

Ciprofloxacin preparations


The SPC now advises that epidemiologic studies report an increased risk of aortic aneurysm and dissection after intake of fluoroquinolones, particularly in the older population.

<https://www.medicines.org.uk/emc/product/4346/smpc>

Cymbalta (duloxetine) capsules

Interstitial lung disease and eosinophilic pneumonia have been reported as rare adverse effects in the SPC.

<https://www.medicines.org.uk/emc/product/3880/smpc>


Proposed action 

Newsletter Optimise Rx/ScriptSwitch

Practice audit/search Other (please specify)

Action taken

Status Action due date Date completed

Unassigned  _____

Depakote (valproic acid) preparations

Haemorrhage (common) and vasculitis (uncommon) have been listed as potential adverse effects of treatment to the SPC.

<https://www.medicines.org.uk/emc/product/6102/smpc>

Epilim (sodium valproate) preparations

Haemorrhage (common) and vasculitis (uncommon) have been listed as potential adverse effects of treatment to the SPC.

<https://www.medicines.org.uk/emc/product/519/smpc>

Lamotrigine

The SPC has been updated to state that Brugada-type ECG is associated with medicine and caution advised in patients with this syndrome. Haemophagocytic lymphohistiocytosis has been reported and updated advice on monitoring breast fed infants is provided.

<https://www.medicines.org.uk/emc/product/6092/smpc>

Latuda (lurasidone) tablets – all strengths

The SPC advises that patients should be counselled on signs and symptoms of elevated prolactin, such as gynecomastia, galactorrhoea, amenorrhoea and erectile dysfunction and be advised to seek medical attention if they experience any of these.

<https://www.medicines.org.uk/emc/product/7549/smpc>

Maxitrol (dexamethasone polymyxin B and neomycin) Eye Drops

Stevens-Johnson Syndrome has been added as a potential adverse effect of treatment (frequency unknown) to the SPC, and use in patients with untreated parasitic eye infections is now contraindicated.

<https://www.medicines.org.uk/emc/product/841/smpc>

Opticrom Aqueous (Sodium Cromoglicate) 2% Eye Drops

The SPC notes that this product contains benzalkonium chloride which has been reported to cause eye irritation, symptoms of dry eyes and may affect tear film and corneal surface therefore use cautioned in patients with dry eyes and compromised corneas.

<https://www.medicines.org.uk/emc/product/9319/smpc>

Optilast (azelastine) Eye Drops

The SPC has been updated to warn that benzalkonium chloride may cause eye irritation, especially with dry eyes or disorders of the cornea.

<https://www.medicines.org.uk/emc/product/1624/smpc>

Relenza (zanamivir) 5mg/dose inhalation powder

Milk protein allergy has been added to SPC as new contraindication, as has precautionary warning to avoid zanamivir during pregnancy and clinician to make a decision whether to continue breastfeeding.

<https://www.medicines.org.uk/emc/product/3809/smpc>

Tamiflu (oseltamivir) products

SPCs has been updated with information on use in immunocompromised patients. The recommended oral treatment dose is 75mg BD for 10 days for adults. For seasonal prophylaxis, longer duration of up to 12 weeks has been evaluated in immunocompromised patients.

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

statusOptions

Unassigned

Red

Amber

Green