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## Medicines Safety Assurance Tool July 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](mailto:mlcsu.medicines-safety@nhs.net)



Midlands and Lancashire  
Commissioning Support Unit

### Combur10 Test UX and Chemstrip 10 A test strips - risk of falsely low results when measuring test strips on the Urisys 1100 urine analyser

Central Alerting System | 05 July 2018

Manufactured by Roche Diagnostics GmbH – Due to incorrect limit of detection (LoD) for protein, nitrite, ketone bodies, leukocytes, blood: intact erythrocytes, patient treatment may be adversely impacted.

<https://www.gov.uk/drug-device-alerts/combur10-test-ux-and-chemstrip-10-a-test-strips-risk-of-falsely-low-results-when-measuring-test-strips-on-the-urisy-1100-urine-analyser>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

### NOACs and Antidepressants - What are the risks of using these together and how should these risks be managed?

Specialist Pharmacy Services | 14 Aug 2018

This article considers the risk of interactions between non-vitamin K antagonist oral anticoagulants (NOACs; also known as direct oral anticoagulants [DOACs]) and antidepressants.

[https://www.sps.nhs.uk/wp-content/uploads/2018/07/SW\\_QA\\_225.2\\_NOACS\\_Antidepress\\_-Final.docx](https://www.sps.nhs.uk/wp-content/uploads/2018/07/SW_QA_225.2_NOACS_Antidepress_-Final.docx)

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

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### Pressurised metered dose inhalers (pMDI): risk of airway obstruction from aspiration of loose objects

Medicines and Health Products Regulatory Agency | 18 July 2018

Due to reports of patients inhaling objects to the back of the throat, healthcare professionals are reminded to counsel patients on the correct use of their inhaler as well as emphasising the need to clean the device regularly.

<https://www.gov.uk/drug-safety-update/pressurised-metered-dose-inhalers-pmdi-risk-of-airway-obstruction-from-aspiration-of-loose-objects>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

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### Resources to support safe and timely management of hyperkalaemia

NHS Improvement | 08 Aug 2018

Hyperkalaemia is a potentially life threatening emergency that can be corrected with treatment. The following resources offer evidence based guidance to help organisations ensure their clinical staff have easily accessible information to guide prompt investigation, treatment and monitoring options for hyperkalaemia.

<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

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## Summary of Product Characteristics Update

Electronic Medicines Compendium | July 2018

### Alimemazine products

The SPC has been updated to add hypersensitivity to phenothiazines, narrow angle glaucoma and history of agranulocytosis as contraindications and has added caution in use in patients with seizures.

<https://www.medicines.org.uk/emc/product/6649/smpc>

### Amorolfine 5% w/v medicated nail lacquer

The SPC states that amorolfine should not be applied on the skin around the nail and that patients should wait at least 10 minutes before application of any cosmetic nail lacquer.

<https://www.medicines.org.uk/emc/product/7414/smpc>

### Arthrotec (diclofenac sodium and misoprostol) tablets

The updated SPC now contains revised warnings relating to teratogenicity with misoprostol use and the possible risks with exposure to diclofenac/non-steroidal anti-inflammatory drugs during pregnancy.

<https://www.medicines.org.uk/emc/product/1144/smpc>

### Betim (timolol) 10mg tablets

The SPC now includes new warnings regarding respiratory disorders, corneal disease, the use with other beta-blocking agents, anaphylactic reactions, choroidal detachment and surgical anaesthesia. An interaction with CYP2D6 inhibitors has also been added.

<https://www.medicines.org.uk/emc/product/1399/smpc>

### Briviact (brivaracetam) tablets

SPC has been updated to reflect the extension in licensing for the use in adolescents and children from 4 years as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation.

<https://www.medicines.org.uk/emc/product/1963/smpc>

### Combined hormonal contraceptives, checklist for prescribers

The purpose of this checklist is to support the safe prescribing and use of various combined hormonal contraceptives including Femodene, Femodette, Qlaira, Triadene, Yasmin, Eloine, Logynon and Microgynon.

<https://www.medicines.org.uk/emc/rmm/611/Document>

Proposed action

Newsletter

Optimise Rx/ScriptSwitch

Practice audit/search

Other (please specify)

Action taken

Status

Unassigned

Action due date

Date completed



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### **Dalacin (clindamycin) – all presentations**

Pseudomembranous colitis has been added to the SPC as an adverse drug reaction with unknown frequency.

<https://www.medicines.org.uk/emc/product/1079/smpc>

### **EpiPen® Auto-Injector & Trainer Pen**

electronic Medicines compendium | 04 Jul 2018

This patient information resources provides a step by step pictographic guide on how to administer the EpiPen or EpiPen Junior device

[http://www.epipen.co.uk/fileadmin/user\\_upload/epipen\\_uk/EPI-2017-0287\\_Guide\\_to\\_Using\\_Your\\_EpiPen\\_4pp\\_V4.pdf](http://www.epipen.co.uk/fileadmin/user_upload/epipen_uk/EPI-2017-0287_Guide_to_Using_Your_EpiPen_4pp_V4.pdf)

### **Humulin I Kwikpen (isophane) 100IU/ml suspension for injection**

The SPC has been revised to state that Humulin I in pre-filled pen is only suitable for subcutaneous injection and the previous statement regarding the possible administration via intramuscular route has been removed.

<https://www.medicines.org.uk/emc/product/8194/smpc>

### **Humulin M3 (biphasic isophane insulin) KiwkPen (Mixture 3) 100IU/ml suspension for injection**

The SPC has been revised to state that Humulin M3 in pre-filled pen is only suitable for subcutaneous injection and the previous statement regarding the possible administration via intramuscular route has been removed.

<https://www.medicines.org.uk/emc/product/8191/smpc>

### **Humalog Mix50 100 units/ml suspension for injection in cartridge**

Ten SPCs have been condensed into 4 combined SPCs which are divided into: 100 u/ml cartridge, vial, KwikPen, Junior Kwikpen, Mix25 100 u/ml cartridge, vial, Kwikpen, Mix50 100 u/ml cartridge, KwikPen, and 200 u/ml KwikPen. The SPC now includes information on the safe use of cartridges/vials.

<https://www.medicines.org.uk/emc/product/7474/smpc>

### **Ibuprofen products**

Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) have been added as potential adverse effects to the SPC with frequency unknown.

<https://www.medicines.org.uk/emc/product/5936/smpc>

### **Jardiance (empagliflozin) tablets**

The SPC has been updated to remove the following statement: 'Jardiance should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis'.

<https://www.medicines.org.uk/emc/product/7703/smpc>

**Jext (adrenaline) 150 and 300 micrograms Solution for Injection in pre-filled pen**

The SPC now advises that if the injection is being performed by a caregiver then the patient should be instructed not to move, and immobilisation of the patient's leg should be ensured, to reduce the risk of laceration. The SPC has been updated to include diagrams in section 6.6.

<https://www.medicines.org.uk/emc/product/5748/smpc>

**Jinarc (tolvaptan) tablets**

The SPC has been updated and includes a contraindication for use in people which have a hypersensitivity to benzazepine or benzazepine derivatives (e.g. benazepril, conivaptan, fenoldopam mesylate or mirtazapine), as they may be at risk for hypersensitivity reaction to tolvaptan.

<https://www.medicines.org.uk/emc/product/6846/smpc>

**Komboglyze (saxagliptin/metformin) tablets**

The dosing for saxagliptin for patients with GFR <30ml/min is no longer contraindicated, and the maximum daily dose is now 2.5mg. Moderate renal impairment is now defined in SPC as GFR >30 to <45mL/min. The SPC also includes updated trial data on renal impairment.

<https://www.medicines.org.uk/emc/product/2920/smpc>

**Lasilactone (20mg furosemide and 50mg spiro lactone) capsules**

There is an additional warning in the SPC which states that for some patients with metastatic castration-resistant prostate cancer, tumour progression has been observed during spiro lactone treatment. It also now states that potency may be impaired with spiro lactone treatment.

<https://www.medicines.org.uk/emc/product/907/smpc>

**Metoject (methotrexate) PEN solution for injection in pre-filled pen**

The SPC has been updated to reflect that this is now additionally licensed for the treatment of moderate to severe psoriasis in adult patients who are candidates for systemic therapy.

<https://www.medicines.org.uk/emc/product/5443/smpc>

**Mogadon (nitrazepam) 5mg tablets**

The SPC has a new warning about the concomitant use with opioids as per CMDh advice. This highlights the risk of sedation/respiratory depression/coma/death; therefore, the concomitant use should be reserved for when other treatments are not possible, at the lowest effective dose for shortest duration.

<https://www.medicines.org.uk/emc/product/3901/smpc>

**Mysimba (naltrexone & bupropion) prolonged release tablets**

Urticaria has been added to the SPC as an uncommon adverse effect of treatment.

<https://www.medicines.org.uk/emc/product/2684/smpc>

**Onglyza (saxagliptin) 2.5mg & 5mg film-coated tablets**

The dosing for saxagliptin for patients with GFR <30ml/min is no longer contraindicated, and the maximum daily dose is now 2.5mg. Moderate renal impairment is now defined in SPC as GFR >30 to <45mL/min. The SPC also includes updated trial data on renal impairment.

<https://www.medicines.org.uk/emc/product/6675/smpc>

**Prostap SR and Prostap 3 DCS (leuprorelin acetate)**

Section 4.8 of the SPC (undesirable effects) has been updated to include interstitial lung disease as a side effect with unknown frequency.

<https://www.medicines.org.uk/emc/product/4651/smpc>

**Protopic (tacrolimus) ointment**

SPC states that butylhydroxytoluene (E321) is an excipient which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

<https://www.medicines.org.uk/emc/product/1612/smpc>

**Samsca (tolvaptan) 15 and 30mg tablets**

The SPC has been updated and includes a contraindication for use in people which have a hypersensitivity to benzazepine or benzazepine derivatives (e.g. benazepril, conivaptan, fenoldopam mesylate or mirtazapine), as they may be at risk for hypersensitivity reaction to tolvaptan.

<https://www.medicines.org.uk/emc/product/6635/smpc>

**Skudexa (tramadol and dexketoprofen) 75mg/25mg film coated tablets**

The SPC has had various sections updated with advice that the dose should be tapered gradually to prevent symptoms of withdrawal and the risks of concomitant use with other sedative medicines.

<https://www.medicines.org.uk/emc/product/8849>

**Suprax (cefixime) tablets 200mg**

The SPC now recommends that the recommended dose is 200-400mg daily according to the severity of infection in adults and children over 10 years or weighing more than 50kg. This can either be given as a single dose or in two divided doses.

<https://www.medicines.org.uk/emc/product/5534/smpc>

**Telfast (fexofenadine hydrochloride) 120, 180mg film coated tablets and 30mg tablets**

The SPC has been updated with information on that no human data on the effect of fexofenadine hydrochloride on fertility are available. However, in mice, there was no effect on fertility with fexofenadine hydrochloride treatment.

<https://www.medicines.org.uk/emc/product/6431/smpc>

**Testogel 16.2mg/g gel**

The SPC now advises that testosterone should be used with caution in patients with thrombophilia as there have been post-marketing reports of thrombotic events in these patients during testosterone therapy.

<https://www.medicines.org.uk/emc/product/8919/smpc>

**Trulicity (dulaglutide) 1.5mg solution for injection in pre-filled pen**

Cholelithiasis and cholecystitis have been added as uncommon adverse drug reactions.

<https://www.medicines.org.uk/emc/product/3634/smpc>

**Vipdomet (alogliptin and metformin) film coated tablets**

SPS now warns of acute pancreatitis as a serious adverse reaction and is attributed to alogliptin, as are hypersensitivity reactions (e.g. Stevens-Johnson syndrome, anaphylactic reactions, angioedema). Lactic acidosis may occur rarely because of metformin.

<https://www.medicines.org.uk/emc/product/5234/smpc>

**Xarelto (rivaroxaban) tablets - all strengths**

DRESS syndrome (Drug reaction with eosinophilia and systemic symptoms) noted in post-marketing reports (frequency very rare). Interaction with fluconazole/ erythromycin/clarythromycin not clinically relevant in most patients but potentially significant in high-risk patients.

<https://www.medicines.org.uk/emc/product/6402/smpc>

**Zebinix (eslicarbazepine) 800mg tablets**

Urticaria, angioedema and severe cutaneous adverse reactions (SCARS) including Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been added as adverse drug reactions with unknown frequency.

<https://www.medicines.org.uk/emc/product/7872/smpc>