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## Medicines Safety Assurance Tool May-18

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Midlands and Lancashire  
Commissioning Support Unit

### Public Health England issues guidance for local areas on planning to deal with illicit fentanyl or other potent opioid entering the market

Public Health England | 08 May 2018

This guide should enable local partners to rapidly understand the scale of the threat of illicit drugs entering the market, and assess the risk, communicate the threat, and take actions to mitigate the threat.

<https://www.gov.uk/government/publications/fentanyl-preparing-for-a-future-threat>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

### Pharmacovigilance Risk Assessment Committee (PRAC) recommends new measures to minimise risk of rare but serious liver injury with ulipristal acetate (Esmya) for fibroids in EU

European Medicines Agency | 21 May 2018

The PRAC has concluded that ulipristal acetate (Esmya) may have contributed to the development of some cases of serious liver injury and must not be used in women with liver problems and that regular liver tests will need to be performed in new patients.

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2018/06/news\\_detail\\_002966.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/06/news_detail_002966.jsp&mid=WC0b01ac058004d5c1)

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

### Valproate medicines (Epilim ▼, Depakote ▼): Pregnancy Prevention Programme materials online

Medicines and Health Products Regulatory Agency | 25 May 2018

The Marketing Authorisation Holder for Epilim has produced new materials to support the Pregnancy Prevention Programme – branded as Prevent. These are available online and will be posted to healthcare professionals in the coming weeks. Once received, dispose of any old materials.

<https://www.gov.uk/drug-safety-update/valproate-medicines-epilim>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

### Braltus (tiotropium): risk of inhalation of capsule if placed in the mouthpiece of the inhaler

Medicines and Health Products Regulatory Agency | 25 May 2018

Two Yellow Card reports of patients who have inhaled a Braltus capsule from the mouthpiece into the back of the throat have been received. Health professionals advised to train patients in correct inhaler technique, store capsules in original bottle and check mouthpiece is clear.

<https://www.gov.uk/drug-safety-update/braltus-tiotropium-risk-of-inhalation-of-capsule-if-placed-in-the-mouthpiece-of-the-inhaler>

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 | May 2018

### Amias (candesartan cilexetil) tablets

Diarrhoea has been added as an adverse effect (frequency not known).

<https://www.medicines.org.uk/emc/product/1355/smpc>

### Avaxim (hepatitis a vaccine, inactivated, adsorbed)

The SPC now details that the use of this vaccine is possible during breast-feeding.

<https://www.medicines.org.uk/emc/product/1394/smpc>

### Aviticol 20 000 IU capsules (colecalciferol)

The shelf-life of this product has been extended from 18 months to 36 months.

<https://www.medicines.org.uk/emc/product/3563/smpc>

### Brilique (ticagrelor) – all formulations

SPC now states that delayed and decreased exposure to oral P2Y12 inhibitors, including ticagrelor (TG) and active metabolite, has been observed in patients with ACS on morphine (35% reduction in TG exposure). May apply to other opioids; clinical relevance unknown.

<https://www.medicines.org.uk/emc/product/5767/smpc>

### Cellcept (mycophenolate mofetil) products

Roche | 04 May 2018

Guide for healthcare providers has been designed to highlight risk of teratogenicity linked to exposure to mycophenolate during pregnancy and to minimise the number of pregnancies during treatment. Patient advises on ways to reduce these risks for the unborn baby.

<https://www.medicines.org.uk/emc/product/1103/rmms>

### Daktacort (hydrocortisone/miconazole nitrate) cream and ointment

SPC notes that visual disturbance (frequency unknown) may be reported with systemic and topical corticosteroid use.

Symptomatic patients should be considered for referral to an ophthalmologist for evaluation of possible causes.

<https://www.medicines.org.uk/emc/product/4652/smpc>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

**Danazol Capsules**

SPC now details that concomitant administration with simvastatin is contraindicated owing to the risk of myopathy and rhabdomyolysis from increased simvastatin levels.

<https://www.medicines.org.uk/emc/product/4379/smpc>

**Efexor XL (venlafaxine) preparations**

SPC has been updated to highlight that in post-marketing experience unintended pregnancies have been reported in subjects taking oral contraceptives while on venlafaxine. There is no clear evidence these pregnancies were a result of a drug interaction with venlafaxine.

<https://www.medicines.org.uk/emc/product/5474/smpc>

**Eltroxin (levothyroxine) tablets**

SPC now describes a potential interaction between ritonavir and levothyroxine. Thyroid-stimulating hormone (TSH) should be monitored in patients treated with levothyroxine at least the first month after starting and /or ending ritonavir treatment.

<https://www.medicines.org.uk/emc/product/434/smpc>

**Epiduo (0.1% adapalene/2.5% benzoyl peroxide) Gel**

Anaphylactic reaction and skin discolouration, (hyperpigmentation and hypopigmentation), urticaria, have been added to SPC as adverse effects.

<https://www.medicines.org.uk/emc/product/451/smpc>

**Estring (estradiol Hemihydrate)**

The SPC has been updated to include a special warning regarding cases of ring adherence to the vaginal wall, and 'vaginal adhesion' has been added as an adverse drug reaction reported during post-marketing surveillance.

<https://www.medicines.org.uk/emc/product/1083/smpc>

**Evotaz (atazanavir and cobicistat) tablets**

SPC now details that concomitant administration with lurasidone is contraindicated (owing to increased levels of lurasidone due to CYP3A4 inhibition).

<https://www.medicines.org.uk/emc/product/7006/smpc>

**Fluconazole preparations**

SPC now details that concomitant administration of olaparib is not recommended. If it cannot be avoided the dose of olaparib should be limited to 200mg twice daily (Fluconazole increases olaparib levels due to CYP3A4 inhibition).

<https://www.medicines.org.uk/emc/product/6086/smpc>

**Imigran Injection, Subject (sumatriptan)**

Section 4.4 now warns that the needle shield of the pre-filled syringe may contain dry natural latex rubber that has the potential to cause allergic reactions in latex sensitive individuals.

<https://www.medicines.org.uk/emc/product/944/smpc>

**Lasilactone (furosemide and spironolactone) capsules**

Lichenoid reactions have been added as an undesirable effect.

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

**Levemir (insulin detemir) products**

SPCs have been revised to highlight that the Penfill, FlexPen and InnoLet products are only suitable for subcutaneous injections from a reusable pen. If administration by syringe is necessary, a vial should be used.

<https://www.medicines.org.uk/emc/product/5536/smpc>

**Maxtrex (methotrexate) tablets – all strengths**

Concomitant administration of levetiracetam and methotrexate has been reported to decrease methotrexate clearance, resulting in increased/prolonged blood methotrexate concentration to potentially toxic levels. Blood methotrexate and levetiracetam levels should be monitored.

<https://www.medicines.org.uk/emc/product/1377/smpc>

**Reyataz (atazanavir) Hard Capsules**

SPC has been revised to include information on the contraindicated co-administration with lurasidone, as atazanavir is expected to increase plasma levels of lurasidone due to CYP3A4 inhibition, potentially increasing risk of lurasidone-related toxicity.

<https://www.medicines.org.uk/emc/product/7739/smpc>

**Sofradex (framycetin Sulphate, dexamethasone sodium metasulphobenzoate, gramicidin) Ear/Eye Drops**

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects, therefore should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects.

<https://www.medicines.org.uk/emc/product/2253/smpc>

**Sominex (promethazine) Tablets**

Information on use in pregnancy and breast-feeding has been updated. It should not be used in pregnancy unless considered essential. Evidence suggests that the amount excreted in milk is insignificant, however, there are risks of neonatal irritability and excitement.

<https://www.medicines.org.uk/emc/product/9010/smpc>

**Stilnoct (zolpidem) 5 and 10mg Film-Coated Tablets**

Following adverse effects have been added to SPC: depression (common); restlessness, aggression, somnambulism, euphoric mood (uncommon); libido disorder (rare); and delusion, dependence [withdrawal symptoms, or rebound effects may occur after treatment discontinuation] (very rare).

<https://www.medicines.org.uk/emc/product/4931/smpc>

**STRIVIT-D3 (colecalfiferol) 800IU Capsules, Soft**

The formulation now contains maize oil instead of arachis oil.

<https://www.medicines.org.uk/emc/product/7231/smpc>

**Trileptal (oxcarbazepine) tablets**

Weight increase has been added as a common adverse effect of treatment.

<https://www.medicines.org.uk/emc/product/3815/smpc>

**Zemon 40 XL Prolonged Release Tablets (isosorbide mononitrate)**

New contraindications include concomitant use with riociguat, due to hypotension, and cerebrovascular insufficiency.

<https://www.medicines.org.uk/emc/product/2135/smpc>

**Zocor (simvastatin) tablets**

Anaphylaxis has been added as a very rare side effect.

<https://www.medicines.org.uk/emc/product/7791/smpc/>

**Zydol (tramadol) – all presentations**

Section 4.4 has been updated to include further information about dependence and treatment discontinuation, CYP2D6 metabolism, post-operative use in children, and use in children with compromised respiratory function.

<https://www.medicines.org.uk/emc/product/81/smpc>