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

### Professional use HIV test: Alere HIV Combo - risk of false positive results

Central Alerting System | 05 Oct 2017

Specific lots are affected, listed in the manufacturer's Field Safety Notice. The alert highlights action to be taken where affected devices have been used, and that organisations should ensure all relevant members of staff receive the manufacturer's Field Safety Notice.

<https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102655>

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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## HIV Pharmacy Association of the UK advises no interaction between the influenza vaccine and antiretrovirals

*HIV Pharmacists Association | 12 Oct 2017*

Following reports that some GP computer systems are giving a 'high severity' warning, the HIV Pharmacy Association is advising that it is safe to give patients on antiretroviral therapy the influenza vaccine without compromising either the vaccine or the patient's HIV treatment.

<http://www.hivpa.org/information-for-healthcare-professionals/>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

## Methylprednisolone injectable medicine containing lactose (Solu-Medrone 40 mg): do not use in patients with cows' milk allergy

*Medicines and Healthcare Regulatory Agency | 26 Oct 2017*

Solu-Medrone 40 mg may contain trace amounts of milk proteins. Do not use in patients with a known or suspected allergy to cows' milk.

<https://www.gov.uk/drug-safety-update/methylprednisolone-injectable-medicine-containing-lactose-solu-medrone-40-mg-do-not-use-in-patients-with-cows-milk-allergy>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

### Gabapentin (Neurontin): risk of severe respiratory depression

Medicines and Healthcare Regulatory Agency | 26 Oct 2017

Gabapentin has been associated with a rare risk of severe respiratory depression even without concomitant opioid medicines. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment, concomitant use of central nervous system (CNS) depressants, and elderly people might be at higher risk of experiencing severe respiratory depression. Dose adjustments might be necessary in these patients.

<https://www.gov.uk/drug-safety-update/gabapentin-neurontin-risk-of-severe-respiratory-depression>

Proposed action

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

[Redacted]

Action taken

[Redacted]

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

### Isotretinoin (Roaccutane): rare reports of erectile dysfunction and decreased libido

Medicines and Healthcare Regulatory Agency | 26 Oct 2017

Cases of sexual dysfunction, predominantly involving erectile dysfunction and decreased libido, have been reported rarely in patients taking oral isotretinoin for severe acne.

<https://www.gov.uk/drug-safety-update/isotretinoin-roaccutane-rare-reports-of-erectile-dysfunction-and-decreased-libido>

Proposed action

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

[Redacted]

Action taken

[Redacted]

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

## Clozapine: reminder of potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus

Medicines and Healthcare Regulatory Agency | 26 Oct 2017

If constipation occurs during treatment with clozapine (Clozaril, Denzapine, Zaponex), it is vital that it is recognised and actively treated.

<https://www.gov.uk/drug-safety-update/clozapine-reminder-of-potentially-fatal-risk-of-intestinal-obstruction-faecal-impaction-and-paralytic-ileus>

Proposed action

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

[Redacted]

Action taken

[Redacted]

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

## Eperzan ▼ (albiglutide): global discontinuation of medicine

Medicines and Healthcare Regulatory Agency | 26 Oct 2017

Do not initiate new patients; transition all current patients to an alternative therapy by July 2018

[https://assets.publishing.service.gov.uk/media/59f081c6e5274a18bc07411b/Eperzan\\_Letter\\_-\\_090917.pdf](https://assets.publishing.service.gov.uk/media/59f081c6e5274a18bc07411b/Eperzan_Letter_-_090917.pdf)

Proposed action

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

[Redacted]

Action taken

[Redacted]

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

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

Medicines and Healthcare Regulatory Agency | 26 Oct 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.gov.uk/drug-device-alerts/all-accu-chek-insight-insulin-pumps-risk-of-alarm-failure>

Proposed action

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



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Action taken

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

## Summary of Product Characteristics Updates

electronic Medicines Compendium | Oct 2017

### Accuretic (quinapril and hydrochlorothiazide) tablets and Accupro (quinapril) tablets

SPC's contraindicate the concomitant use of quinapril with sacubitril/valsartan due to increased risk of angioedema.

Concomitant use of other neutral endopeptidase (NEP) inhibitors (e.g. racecadotril) and ACE inhibitors may also increase risk of angioedema.

<http://www.medicines.org.uk/emc/medicine/13295>

### Adartrel (ropinirole) tablets

Sections 4.4 and 4.8 have been updated with warnings on the risk of hallucinations (uncommon adverse event) with dopamine agonists and levadopa.

<http://www.medicines.org.uk/emc/medicine/17844>

### Azilect (rasagiline) tablets

SPC now highlights, that owing to somnolence, patients should be informed not to engage in activities where impaired alertness may put themselves or other at risk of injury (e.g. operating machines) until they have gained sufficient experience to gauge whether it affects them.

<http://www.medicines.org.uk/emc/medicine/16273>

### Bosentan 62.5 mg & 125 mg film-coated tablets (all brands)

The SPCs have been updated to warn that bosentan (125 mg twice daily) reduced tadalafil (40 mg once per day) systemic exposure by 42% and Cmax by 27% following multiple dose co-administration. Tadalafil did not affect the exposure (AUC and Cmax) of bosentan or its metabolites.

<http://www.medicines.org.uk/emc/medicine/20423>

### Calcichew D3 Chewable Tablets

Sorbitol and aspartate are no longer excipients of this preparation. The note that calcichew D3 Forte may be harmful for people with phenylketonuria (due to aspartame content) has therefore been removed.

<http://www.medicines.org.uk/emc/medicine/28504>

Proposed action

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



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Action taken

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

**Co-Aprovel (irbesartan and hydrochlorothiazide) tablets**

Thrombocythaemia has been added as a potential adverse effect of treatment (frequency unknown).

<http://www.medicines.org.uk/emc/medicine/26490>

**Constella (linaclotide) 290 micrograms hard capsules**

Section 4.5 now advises caution with co-administration of linaclotide with proton pump inhibitors, laxatives or NSAIDs, as concomitant administration of these may increase the risk of diarrhoea.

<http://www.medicines.org.uk/emc/medicine/31618>

**Dolmatil (sulpiride) tablets**

Pneumonia aspiration (mainly in association with other CNS depressants) has been added as a potential adverse effect of treatment (frequency unknown). Constipation has also been added as a common adverse reaction.

<http://www.medicines.org.uk/emc/medicine/24603>

**Duodopa (levodopa and carbidopa) intestinal gel**

Angle closure glaucoma has been added to the table of undesirable side effects (uncommon frequency).

<http://www.medicines.org.uk/emc/medicine/20786>

**Eliquis (apixaban) 2.5 and 5.0 mg film-coated tablets**

SPC has been updated with information on concomitant use with clarithromycin (500 mg twice a day), an inhibitor of P-gp and a strong inhibitor of CYP3A4, leading to a 1.6-fold and 1.3-fold increase in mean apixaban AUC and C<sub>max</sub> respectively.

<http://www.medicines.org.uk/emc/medicine/24988>

**Eumovate (clobetasone butyrate) Cream**

Following PRAC recommendation, SPC now states visual disturbance may be reported with systemic/topical corticosteroid use and referral to ophthalmologist for evaluation of possible causes (e.g. cataract, glaucoma, central serous chorioretinopathy) may be needed.

<http://www.medicines.org.uk/emc/medicine/2606>

**Femodette, Femodene, Triadene (gestodene and ethinylestradiol) tablets**

SPC's contraindicate the concomitant use of the above contraceptives with ombitasvir, paritaprevir, ritonavir or dasabuvir due to clinically significant drug interactions and increased risk of ALT elevations.

<http://www.medicines.org.uk/emc/medicine/2542>

**Genvoya (elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide fumarate) film coated tablets**

Updates to section 4.5 include a new note that in vitro and clinical pharmacokinetic drug-drug interaction studies have shown that the potential for CYP-mediated interactions involving tenofovir alafenamide with other medicinal products is low.

<http://www.medicines.org.uk/emc/medicine/31225>

**Glivec (imatinib) film-coated tablets**

SPC has been updated to include results of observational study in CML paediatric population, showing statistically significant decrease (but uncertain clinical relevance) in median height standard deviation scores after 12 and 24 months of treatment in 2 small patient subsets.

<http://www.medicines.org.uk/emc/medicine/15014>

**Haldol (haloperidol decanoate) solution for injection**

Following a review by the EMA, indications have been harmonised across all member states. Haloperidol decanoate is now specifically licensed for use for maintenance treatment of schizophrenia and schizoaffective disorder in adults stabilised with oral haloperidol.

<http://www.medicines.org.uk/emc/medicine/904>

**Iclusig (ponatinib) 15mg 30mg and 45mg film-coated tablets**

The SPC has been updated with the addition of a new 30mg strength film-coated tablets which is expected to be launched on 1st October 2017.

<http://www.medicines.org.uk/emc/medicine/28145>

**Pariet (rabeprazole) 10mg & 20mg**

Microscopic colitis has been added as an adverse event (frequency unknown).

<http://www.medicines.org.uk/emc/medicine/2577>

**Pericyazine tablets and syrup**

The SPC has been updated to note the possible pharmacokinetic interaction between inhibitors of CYP2D6, such as phenothiazines, and CYP2D6 substrates.

<http://www.medicines.org.uk/emc/medicine/26089>



**Renvela (sevelamer carbonate) 800 mg film coated tablets**

Renvela is now licensed for the control of hyperphosphataemia in paediatric patients (>6 years of age and a Body Surface Area (BSA) of >0.75m<sup>2</sup>) with chronic kidney disease. The entire SPC has been updated to reflect information pertaining to this new indication.

<http://www.medicines.org.uk/emc/medicine/22781>

**Revlimid (lenalidomide)**

The SPC has been updated to include a warning about the risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS; unknown frequency) and a dose modification in case of DRESS.

<http://www.medicines.org.uk/emc/medicine/19841>

**Roaccutane (isotretinoin) 10mg and 20mg Soft Capsules**

Sexual dysfunction including erectile dysfunction and decreased libido have been added to SPC as adverse effects of unknown frequency.

<http://www.medicines.org.uk/emc/medicine/1727>

**Sinemet (levodopa/carbidopa) products**

Dopamine dysregulation syndrome has been added as new adverse effect. This is an addictive disorder seen in some patients treated with carbidopa/ levodopa, where they show compulsive pattern of dopaminergic drug misuse above doses adequate to control motor symptoms.

<http://www.medicines.org.uk/emc/medicine/9647>

**Suprax (cefixime) tablets 200 mg**

SPC now highlights that convulsions have been reported with cephalosporins, and this has been added as a potential adverse effect of treatment (frequency unknown).

<http://www.medicines.org.uk/emc/medicine/14540>

**Surgam (Tiaprofenic Acid) 300mg tablets**

The SPC has been updated to note that in patients concomitantly receiving nicorandil and NSAIDs, there is an increased risk for severe complications such as gastrointestinal ulceration, perforation and haemorrhage.

<http://www.medicines.org.uk/emc/medicine/13287>

**Synflorix (Pneumococcal/ haemophilus influenzae/ tetanus/ diphtheria) injection**

SPC now includes advice on use in patients with splenic dysfunction and has it has clarified that 3 dose schedule should be given as primary vaccination in infants starting vaccination before 6 month of age.

<http://www.medicines.org.uk/emc/medicine/22743>

**Tobradex (tobramycin and dexamethasone) Eye Drops**

Cushing's syndrome and adrenal suppression have been added as potential adverse effects of treatment (frequency unknown).

<http://www.medicines.org.uk/emc/medicine/4670>

**Translarna (ataluren)**

Section 4.5 now notes that in a clinical study, the extent of exposure for ciprofloxacin was 32% higher in the presence of ataluren (the SPC already notes that caution should be exercised when ataluren is co-administered with OAT3 substrates, such as ciprofloxacin).

<http://www.medicines.org.uk/emc/medicine/33294>

**Vimpat (Lacosamide) preparations**

SPC has been updated to highlight that lacosamide is now licensed for partial-onset seizures with or without secondary generalisation in adolescents and children from 4 years of age.

<http://www.medicines.org.uk/emc/medicine/32693>