

Please note that the information in this Safety log is correct at the time of publication. Clinicians should always refer to the most up to date information.

Copyright © Midlands and Lancashire Commissioning Support Unit

## Medicines Safety Assurance Tool October 2019

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

### Class 4 Medicines Defect Information: Emerade 150, 300 and 500 microgram solution for injection in pre-filled syringe (MDR 57-08/19)

Central Alerting System / 03 October 2019

The MHRA has notified Bausch and Lomb UK Limited of reports that Emerade pens have failed to activate. The MHRA is advising that Emerade devices should not be recalled.

<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102896>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

### Glucosamine – what are its drug interactions?

Specialist Pharmacy Service

This updated medicine Q&A considers the limited information available on potential drug interactions between glucosamine and conventional medicines.

<https://www.sps.nhs.uk/articles/glucosamine-what-are-its-drug-interactions/>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

---

### Drug treatment requiring effective contraception

Midlands and Lancashire Commissioning Support Unit / 18 October 2019

A drug safety supplement has been produced by Midlands and Lancashire Commissioning Support Unit which provides advice on drug treatment that requires effective contraception.

[Drug safety supplement](#)

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

---

### Ingenol mebutate gel (Picato ▼): increased incidence of skin tumours seen in some clinical studies

Medicines and Healthcare products Regulatory Agency / 21 October 2019

Advise patients treated with ingenol mebutate gel to be vigilant for new skin lesions and to seek medical advice immediately should any occur. Use with caution in patients with a history of skin cancer.

<https://www.gov.uk/drug-safety-update/ingenol-mebutate-gel-picato-increased-incidence-of-skin-tumours-seen-in-some-clinical-studies>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

---

## Prescribing medicines in renal impairment: using the appropriate estimate of renal function to avoid the risk of adverse drug reactions

Medicines and Healthcare products Regulatory Agency / 21 October 2019

For most patients and most medicines, estimated Glomerular Filtration Rate (eGFR) is an appropriate measure of renal function for determining dosage adjustments in renal impairment; however, in some circumstances, the Cockcroft-Gault formula should be used to calculate creatinine clearance (CrCl).

<https://www.gov.uk/drug-safety-update/prescribing-medicines-in-renal-impairment-using-the-appropriate-estimate-of-renal-function-to-avoid-the-risk-of-adverse-drug-reactions>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

---

## Adrenaline auto-injectors: recent actions taken to support safety

Medicines and Healthcare products Regulatory Agency / 21 October 2019

This article provides a summary of recent advice issued to healthcare professionals, including information to provide to patients, to support safe use of adrenaline auto-injectors.

<https://www.gov.uk/drug-safety-update/adrenaline-auto-injectors-recent-action-taken-to-support-safety>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

---

## MHRA urging GP practices to register for safety alerts on its portal

NHS Networks

Since 1 October, the MHRA started sending safety alerts directly to practices from its central alerting system (CAS), which replaces local email alerting arrangements. CAS will be one of the main channels used to communicate information during EU exit.

[https://www.networks.nhs.uk/news/practices-must-register-for-safety-alerts-says-mhra/newsitem\\_popview](https://www.networks.nhs.uk/news/practices-must-register-for-safety-alerts-says-mhra/newsitem_popview)

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 update

electronic Medicines Compendium / October 2019

### Canesten (fluconazole) Thrush Oral Capsule 150mg capsule

Breastfeeding advice revised to advise that breastfeeding may be maintained after a single dose of 150mg fluconazole but is not recommended after repeated use.

<https://www.medicines.org.uk/emc/product/40/smpc>

### Cellcept (mycophenolate) products

SPCs updated to state no data are available for treatment of first or refractory rejection in paediatric transplant patients and to advise that pharmacokinetics of have not been found to be altered in elderly patients (≥ 65 years) when compared to younger transplant patients.

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

### Ciprallex (escitalopram) film-coated tablets (all strengths)

Section 4.4 of the SPC has been updated to warn serotonin reuptake inhibitors (SSRIs)/serotonin norepinephrine reuptake inhibitors (SNRIs) may cause symptoms of sexual dysfunction which may continue despite discontinuation of SSRIs/SNRI.

<https://www.medicines.org.uk/emc/product/7718/smpc>

### Eliquis (apixaban) film-coated tablets (all strengths)

SPCs state that for situations when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding, a reversal agent for factor Xa inhibitors is now available (andexanet alfa).

<https://www.medicines.org.uk/emc/product/4756/smpc>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

### **Empagliflozin products (Jardiance, Synjardy, Glyxambi)**

SPCs updated to state treatment should be interrupted in patients hospitalised for major surgical procedures/acute serious medical illnesses and monitoring of ketones recommended (blood preferred to urine levels), and treatment restarted when ketones normal and patient stabilised

<https://www.medicines.org.uk/emc/product/5441/smpc>

### **Keppra (levetiracetam) products**

SPCs updated to warn that levetiracetam may cause psychotic symptoms and behavioural abnormalities including irritability and aggressiveness. If such behaviours are noticed, treatment adaptation or gradual discontinuation should be considered.

<https://www.medicines.org.uk/emc/product/2291/smpc>

### **Matrifen (fentanyl) Transdermal patch (all strengths)**

Androgen deficiency and delirium have been added as adverse effects of treatment of unknown frequency to the SPC.

<https://www.medicines.org.uk/emc/product/10272/smpc>

### **Plavix (clopidogrel) tablets**

SPC now details that co-administration of opioids has the potential to delay and reduce the absorption of clopidogrel due to delayed gastric emptying. The use of parenteral antiplatelet agent in ACS should be considered where opioid co-administration is required.

<https://www.medicines.org.uk/emc/product/5934/smpc>

### **Propecia (finasteride) 1mg tablets**

Haematospermia (visible presence of blood in the semen) has been added as an adverse effect of treatment of unknown frequency to the SPC.

<https://www.medicines.org.uk/emc/product/2194/smpc>

### **Renagel and Renvela (sevelamer hydrochloride) preparations**

The following have been listed as potential adverse effects of treatment (frequency unknown) to the SPC: gastrointestinal haemorrhage, intestinal ulceration, gastrointestinal necrosis, colitis and intestinal mass.

<https://www.medicines.org.uk/emc/product/207/smpc>

### **Victoza (liraglutide) 6 mg/ml solution for injection in pre-filled pen**

The SPC has been updated to include delayed gastric emptying as an uncommon ( $\geq 1/1,000$  to  $< 1/100$ ) adverse effect of treatment.

<https://www.medicines.org.uk/emc/product/6585/smpc>

### **Voltarol Rapid (diclofenac) 50 mg Tablets**

SPC warns of risk of Kounis syndrome (frequency not known), a serious allergic reaction that can result in myocardial infarction and an increased risk of gastro-intestinal anastomotic leak which requires caution if using diclofenac after gastro-intestinal surgery.

<https://www.medicines.org.uk/emc/product/4333/smpc>

**Zanidip (lercanidipine) – all strengths**

The SPC contraindicates use in recent myocardial infarction, severe renal impairment and use with grapefruit. Lercanidipine has been associated with the development of cloudy peritoneal effluent in patients on peritoneal dialysis which could be mistaken for infective peritonitis.

<https://www.medicines.org.uk/emc/product/193/smpc>

**Zocor (simvastatin) film-coated tablets- all strengths**

The SPC now warns that cases of myopathy and/or rhabdomyolysis have been reported with HMG-CoA reductase inhibitors (e.g. simvastatin) co-administered with daptomycin.

<https://www.medicines.org.uk/emc/product/1010/smpc>

**Zispin (mirtazapine) SolTab Orodispersible Tablets- all strengths**

Hyperprolactinaemia (and related symptoms galactorrhea and gynecomastia) has been added to SPC as an undesirable effect (unknown frequency).

<https://www.medicines.org.uk/emc/product/6505/smpc>