

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

January 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

### Tapentadol (Palexia): risk of seizures and reports of serotonin syndrome when co-administered with other medicines

Medicines and Healthcare products Regulatory Agency | 10 January 2019

A safety alert has been issued, advising Seizure (SZ) risk is a recognised adverse reaction for all opioids. However, a recent review of safety data for tapentadol in EU identified need for strengthened advice about this risk. It should be prescribed with care in patients with a history of SZ disorders or epilepsy.

<https://www.gov.uk/drug-safety-update/tapentadol-palexia-risk-of-seizures-and-reports-of-serotonin-syndrome-when-co-administered-with-other-medicines>

Proposed action

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



Text area for proposed action details.

Action taken

Text area for action taken details.

Status: Unassigned (dropdown) | Action due date: [ ] | Date completed: [ ]

### FreeStyle Libre flash glucose sensor - Use of barrier methods to reduce skin reactions to the sensor adhesive

Medicines and Healthcare products Regulatory Agency | 29 January 2019

Manufactured by Abbott – some users who are experiencing an immune response to the adhesive are applying creams, patches or sprays under their sensor to reduce skin reactions, which may affect device performance.

<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102829>

Proposed action

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



Text area for proposed action details.

Action taken

Text area for action taken details.

Status: Unassigned (dropdown) | Action due date: [ ] | Date completed: [ ]

## Summary of Product Characteristics Update

electronic Medicines Compendium | January 2019

### Ativan (lorazepam) Injection

The SPC has been revised to warn that lorazepam should be used with caution in elderly due to the risk of sedation and/or musculoskeletal weakness that can increase risk of falls, with serious consequences. These patients should be given a reduced dose (50%) and titrated accordingly.

<https://www.medicines.org.uk/emc/product/5473/smpc>

### Beconase (beclometasone) Hayfever Relief for Adults Nasal Spray

The SPC has been updated to reflect that the storage conditions have now changed from below 30C to below 25C.

<https://www.medicines.org.uk/emc/product/26/smpc>

### Ciproxin (ciprofloxacin) preparations

SPCs detail increased risk of aortic aneurysm and dissection (AA). Fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients with pre-existing disease or risk factors for AA.

<https://www.medicines.org.uk/emc/product/3796/smpc>

### Co-cyprindiol (cyproterone acetate/ethinylestradiol)

Risk minimisation materials include a patient alert card containing important safety information and a prescribing checklist for health care professionals.

<https://www.medicines.org.uk/emc/rmm/1333/Document>

### Depo-Medrone (methylprednisolone) with lidocaine

The SPC notes that glucocorticoid therapy may mask peritonitis or other signs or symptoms associated with gastrointestinal disorders such as perforation, obstruction or pancreatitis. Various adverse drug effects were added and the information on use in pregnancy has been updated.

<https://www.medicines.org.uk/emc/product/1081/smpc>

### Efient (prasugrel) 5 mg 10 mg film-coated tablets

SPCs have been updated to advise a delayed and decreased exposure to oral P2Y12 inhibitors, including prasugrel and active metabolite, has been observed in patients with ACS treated with morphine. This interaction may be related to reduced GI motility and apply to other opioids.

<https://www.medicines.org.uk/emc/product/7860/smpc>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

**Femodette (gestodene and ethinylestradiol) tablets**

The SPC has been updated to highlight that depressed mood is an undesirable effect of hormonal contraceptive use and can be serious and is a risk factor for suicide. Women should contact their doctor if they develop mood changes after starting treatment.

<https://www.medicines.org.uk/emc/product/3798/smpc>

**Ferrous Sulfate Tablets 200mg tablets (Sandoz)**

SPC adds: aspiration of FeSO<sub>4</sub> tablets can cause necrosis of the bronchial mucosa which may result in coughing, haemoptysis, bronchostenosis or pulmonary infection. Elderly patients and those with swallowing difficulties should only be treated after risk assessment of aspiration.

<https://www.medicines.org.uk/emc/product/4231/smpc>

**Flixotide (fluticasone) products**

SPCs now state that the results from a retrospective epidemiological study did not find an increased risk of major congenital malformations following exposure to fluticasone propionate when compared to other inhaled corticosteroids, during the first trimester of pregnancy.

<https://www.medicines.org.uk/emc/product/3824/smpc>

**Froben (flurbiprofen) Tablets 100 mg**

The SPC has been updated with Special warnings and precautions for use revised to include more detailed advice regarding undesirable effects pertaining to; gastrointestinal, immune system, skin and subcutaneous tissue disorders, as well as infections and risk of aseptic meningitis.

<https://www.medicines.org.uk/emc/product/327/smpc>

**Fostair 200/6 (beclomethasone/formoterol) inhalation solution**

Section 4.4 of the SPC has been updated and advises that visual disturbance may be reported with systemic/topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist.

<https://www.medicines.org.uk/emc/product/5076/smpc>

**Gatalin (galantamine hydrobromide) – all formulations**

SPC adds that cholinomimetics may have vagotonic effects on heart rate, including bradycardia and all types of atrioventricular node block and is of importance in cardiac conduction disturbances, electrolyte disturbances, or with medicines that significantly reduce heart rate.

<https://www.medicines.org.uk/emc/product/1271/smpc>

**Hydrea (hydroxycarbamide) 500 mg Hard Capsules**

Section of the SPC on skin cancer risk now advises patients should also conduct self-inspection of skin after stopping therapy. SPC also now warns that interstitial lung disease has been reported in patients treated for myeloproliferative neoplasm and may be linked to fatal outcome.

<https://www.medicines.org.uk/emc/product/271/smpc>

**Latuda (lurasidone) film-coated tablets- all strengths**

SPC has been updated to warn that co-administration of lurasidone (LR) and posaconazole (PS), a strong CYP3A4 inhibitor, resulted in ~ 4-5 fold increase in LR exposure. A persistent effect of PS on LR exposure was observed up to 2-3 weeks after cessation of PS co-administration.

<https://www.medicines.org.uk/emc/product/7551/smpc>

**Lescol (fluvastatin) XL 80 mg Prolonged Release Tablets**

Diarrhoea (unknown frequency) has been added to the SPC as an adverse effect.

<https://www.medicines.org.uk/emc/product/3852/smpc>

**Levosert (levonorgestrel) 20 micrograms/24 hours IDS**

SPC has been updated to advise that Levosert is effective for 5 years in the indications for contraception and heavy menstrual bleeding and thus should be removed after 5 years of use (previously 4 years). Release of levonorgestrel declines progressively by ~50% after 5 years.

<https://www.medicines.org.uk/emc/product/1789/smpc>

**Lipitor (atorvastatin) film-coated tablets (all strengths)**

SPCs have been updated to advise that co-administration with products containing glecaprevir or pibrentasvir is contraindicated; and in patients taking hepatitis C antiviral agents elbasvir/grazoprevir, dose of atorvastatin should not exceed 20 mg/day.

<https://www.medicines.org.uk/emc/product/1059/smpc>

**Lodine (etodolac) SR**

The SPC has been updated with information on aseptic meningitis, a serious but rare adverse drug event that may occur in patients with other auto-immune conditions such as systemic lupus erythematosus or mixed connective tissue disease.

<https://www.medicines.org.uk/emc/product/3857/smpc>

**Moventig (naloxegol) 12.5 mg and 25mg tablets**

The SPC has been updated to warn that use of naloxegol with another opioid antagonist (e.g. naltrexone, naloxone) should be avoided due to the potential for an additive effect of opioid receptor antagonism and an increased risk of opioid withdrawal.

<https://www.medicines.org.uk/emc/product/6892/smpc>

**Mudin (theophylline) SA Tablets**

**niacin (nicotinamide) SA tablets**

Recent myocardial infarction and acute tachyarrhythmia have been added as contra-indications to treatment, and hyperglycaemia, hyperuricaemia and electrolyte imbalance have been added as potential adverse effects of treatment to the SPC.

<https://www.medicines.org.uk/emc/product/9522/smpc>

**Nimenrix (meningococcal group A, C, W-135 and Y conjugate vaccine) powder and solvent for solution for injection in pre-filled syringe**

A warning has been added to SPC about an increased risk of invasive disease caused by Neisseria meningitidis group A, C, W-135 and Y.

<https://www.medicines.org.uk/emc/product/4118/smpc>

**Niquitin (nicotine) transdermal patch – all formulations**

The SPC advises that nicotine replacement therapy may exacerbate symptoms in persons suffering from active oesophagitis, oral and pharyngeal inflammation, gastritis, gastric ulcer or peptic ulcer. Also if applied properly, water will not harm the patch.

<https://www.medicines.org.uk/emc/product/5595/smpc>

**Scopoderm (hyoscine) 1.5mg Patch**

SPC revised to include new information explaining that central actions of scopolamine in high doses are similar to those of atropine.

<https://www.medicines.org.uk/emc/product/3276/smpc>

**Palexia (tapentadol) - all formulations**

The SPC has been updated with information on the risk from concomitant use of sedating medicinal products such as benzodiazepines or related substances.

<https://www.medicines.org.uk/emc/product/5346/smpc>

**Rifadin (rifampicin) products**

SPC has been revised to warn that rifampicin may cause vitamin K dependent coagulopathy and severe bleeding. Monitoring is recommended for patients at particular bleeding risk. Supplemental vitamin K should be considered when appropriate (vit K deficiency, hypoprothrombinemia).

<https://www.medicines.org.uk/emc/product/6384/smpc>

**Trumenba (meningococcal group B vaccine)**

The SPC has been updated with a warning about an increased risk of invasive disease caused by *Neisseria meningitidis* serogroup B in persons with complement deficiencies or using concomitant treatments inhibiting terminal complement activation.

<https://www.medicines.org.uk/emc/product/2670/smpc>

**Virgan (ganciclovir)**

SPC states Virgan contains benzalkonium chloride which may cause eye irritation, especially in dry eyes or corneal disorders. It may also be absorbed by soft contact lenses and may change their colour so they should be removed prior to application and not reinserted for  $\geq 15$  min.

<https://www.medicines.org.uk/emc/product/4674/smpc>

**Zimovane/LS (zopiclone) tablets**

The SPC has reinforced warnings on the risks of abuse and dependence with long term therapy. Risk of abuse and dependence is also greater in psychiatric disorders and/or alcohol, substance or drug abuse. Treatment should not exceed 4 weeks including the period of tapering off.

<https://www.medicines.org.uk/emc/product/2854/smpc>

**Zostavax (varicella-zoster virus, live, attenuated vaccine)**

The SPC has been revised to include data collected from a large observational study which did not indicate an increased risk for developing herpes zoster after concomitant administration of Zostavax and a 23-valent pneumococcal polysaccharide vaccine.

<https://www.medicines.org.uk/emc/product/6101/smpc>

**Zyprexa tablets and velotabs (olanzapine) – all strengths**

Stuttering has now been added to the SPC as an uncommon adverse effect.

<https://www.medicines.org.uk/emc/product/7904/smpc>

















statusOptions  
Unassigned  
Red  
Amber  
Green