

## Medicines Safety Assurance Tool

November 2020

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

### [DTB forum: How do your patients use their medicines at home and why is it important to know?](#)

Article concludes medicines administration at home is a safety issue and given the risk of unsafe or suboptimal practice in the administration of medicines at home, all healthcare professionals should ask patients and carers how medicines are taken or given in that setting.

Proposed action

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



[Redacted content]

Action taken

[Redacted content]

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

### [Modafinil \(Provigil\): increased risk of congenital malformations if used during pregnancy](#)

17 November 2020

Modafinil potentially increases the risk of congenital malformations when used in pregnancy. Modafinil should not be used during pregnancy and women of childbearing potential must use effective contraception during treatment and for 2 months after stopping modafinil.

Proposed action

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



[Redacted content]

Action taken

[Redacted content]

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

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### [Bupropion \(Zyban\): risk of serotonin syndrome with use with other serotonergic drugs](#)

17 November 2020

Cases of serotonin syndrome have been identified in associated with bupropion, especially in overdose or when bupropion is administered with other drugs with a serotonergic effect.

Proposed action

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



[Redacted content]

Action taken

[Redacted content]

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

### [Update to information on psychiatric disorders for chloroquine and hydroxychloroquine](#)

27 November 2020

EMA's safety committee (PRAC) has recommended updating product information for all chloroquine or hydroxychloroquine-containing medicines following a review that confirmed a link between the use of these medicines and the risk of psychiatric disorders and suicidal behaviour.

Proposed action

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



[Redacted content]

Action taken

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### Summary of Product Characteristics updates

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#### Carbocisteine 375 mg Capsules, Hard

New adverse reactions added to the SPC include allergic skin eruption, diarrhoea, nausea and epigastric discomfort.

#### Cardicor (bisoprolol) tablets

Angioedema has been added as a potential adverse effect of treatment (frequency – rare).

#### Cerazette (desogestrel) 75 microgram film-coated tablet

SPC now states that Cerazette can be used during breastfeeding although infrequent post marketing reports suggest a decrease in milk production.

#### Ciproxin (ciprofloxacin) preparations

SPC has been updated following PRAC recommendation to include detail on the increased risk of aortic aneurysm and dissection, and of aortic and mitral valve regurgitation with fluoroquinolones. They should only be used after careful benefit-risk assessment.

#### Duotrav (travoprost and timolol) eye drops

Hallucinations have been added as a potential adverse effect of treatment (frequency unknown).

#### Elvanse (lisdexamfetamine) hard capsules (all strengths)

Lisdexamfetamine has been shown to prolong the QTc interval (frequency unknown). It should be used with caution in patients: 1) with QTc prolongation, 2) treated with drugs affecting the QTc interval, or 3) with relevant pre-existing cardiac disease or electrolyte disturbances.

Proposed action

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 Practice audit/search  Other (please specify)



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### Feldene (piroxicam) products

SPC now warns that Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome) have been reported very rarely in association with the use of NSAIDs.

### Forxiga (dapagliflozin) – all presentations

SPC –details license extension for use in symptomatic chronic heart failure with reduced ejection fraction in adults. Dapagliflozin has not been studied for the treatment of heart failure in pts with type 1 diabetes mellitus, therefore not recommended in this patient cohort.

### Fycompa (perampanel)– all presentations

SPC updated to include details for the licence extension adjunctive use in children aged 4 years, and for partial-onset seizures and from 7 years for idiopathic generalised epilepsy.

### Galzemic (galantamine hydrobromide) 4 mg/ml Oral Solution

SPC warns galantamine can cause bradycardia (common) and all types of atrioventricular node block (rare); and galantamine bioavailability increases during co-administration of paroxetine (CYP2D6 inhibitor), ketoconazole & erythromycin (CYP3A4 inhibitors) have been observed.

### Granpidam (sildenafil) 20 mg film-coated tablets

SPC advises that sildenafil should not be used in neonates with persistent pulmonary hypertension of the newborn as risks outweigh the benefits. The safety and efficacy of sildenafil in other conditions in children below 1 year of age has not been established.

### Imvaggis (estriol) 0.03 mg Pessary

SPC notes epidemiological evidence from a large meta-analysis suggests no increase in risk of breast cancer in women with no history of breast cancer taking low dose vaginally applied estrogens. It is unknown if low dose vaginal estrogens stimulate recurrence of breast cancer.

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### Janumet (sitagliptin/ metformin) 50 mg/1000 mg film-coated tablets

The SPC has been updated to note that it should not be used in people aged 10-17 years because of insufficient efficacy. Safety and pharmacokinetic data from studies in this age group have been added.

### Kigabeg (vigabatrin) 100 and 500 mg soluble tablets

Insomnia and alopecia (frequency “common”) and reduced visual acuity (frequency “not known”) have been to SPC as adverse effects.

### Moviprep (macrogol) powder for oral solution

SPC now advises there have been post-marketing cases of ischaemic colitis with macrogol. It should be used with caution in patients with known risk factors for ischaemic colitis or in case of concomitant use of stimulant laxatives (such as bisacodyl or sodium picosulfate).

### Ovestin (estriol) cream

SPC now states that epidemiological evidence from a large meta-analysis suggests no increased risk of breast cancer in women with no history of breast cancer taking low dose vaginal oestrogens, but it is unknown if low dose vaginal oestrogens stimulate breast cancer recurrence.

### Palladone SR (hydromorphone) capsules

Severe bronchial asthma is a new contraindication, and sleep apnoea syndrome has been added as an adverse event. Use in patients with constipation and head injury is cautioned.

### Phenergan (promethazine) tablets- all strengths

Restless legs syndrome has been added to SPC as adverse effect.

### Plenvu (macrogol) powder for oral solution

SPC now now advises there have been post-marketing cases of ischaemic colitis with macrogol. It should be used with caution in patients with known risk factors for ischaemic colitis or in case of concomitant use of stimulant laxatives (such as bisacodyl or sodium picosulfate).

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### [Prolia \(denosumab\) 60 mg solution for injection in pre-filled syringe](#)

Hypersensitivity vasculitis has been added as a very rare side-effect.

### [Ropilynz \(ropinirole hydrochloride\) XL Prolonged-release Tablets \(all strengths\)](#)

To discontinue treatment in patients with Parkinson's disease, ropinirole should be tapered off, as patients with impulse control disorders and those receiving high daily dose and/or cumulative doses may be at higher risk for developing dopamine agonist withdrawal syndrome.

### [Ropilynz XL \(ropinirole\) 8 mg Prolonged-release Tablets](#)

SPC updated with information on dopamine agonist withdrawal syndrome, which has been reported with dopamine agonists, including ropinirole. Limited data suggests those with impulse control disorders and those receiving high daily and/or cumulative doses may be at higher risk.

### [Setofilm \(ondansetron\) Orodispersible Films](#)

Toxic skin eruption, including toxic epidermal necrolysis, has been added as a very rare adverse event.

### [Sevredol \(morphine\) tablets- all strengths](#)

Sleep apnoea syndrome has been added to SPC as a possible side effect of unknown frequency.

### [Shortec \(oxycodone\) Hard Capsules](#)

Exercise caution in those with intracranial lesions or reduced level of consciousness of uncertain origin. Sleep apnoea syndrome has been added as an adverse event and warnings regarding concomitant use of benzodiazepines and MAOIs within previous 2 weeks have been updated.

### [Trulicity \(dulaglutide\) solution for injection in pre-filled pen](#)

The SPC has been updated to note the 1.5mg dose may be increased after at least 4 weeks to 3mg once daily and the 3mg dose to 4.5mg daily, for additional glycaemic control. Information relating to a 52-week study investigating dulaglutide 3mg and 4.5mg once weekly has been added.

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.

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### Zyban (bupropion) 150 mg prolonged release tablets

SPC warns of risk of serotonin syndrome when co-administered with selective serotonin reuptake inhibitors/serotonin norepinephrine re-uptake inhibitors. If concomitant treatment is required, careful observation is advised, particularly during treatment initiation/dose increases.