

## Medicines Safety Assurance Tool

February 2021

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)

### Opioid safety: striking the right balance

08 February 2021

Editorial discusses difficulties in balancing benefits of treatment in limited life expectancy against risks of opioid addiction with long term use and adds that healthcare professionals will need to be aware of the patient's circumstances to avoid giving conflicting advice.

Proposed action

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



Action taken

Status	Action due date	Date completed
Unassigned		

### Pregabalin (Lyrica): reports of severe respiratory depression

18 February 2021

Pregabalin has been associated with infrequent reports of severe respiratory depression, including some cases without the presence of concomitant opioid medicines.

Proposed action

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



Action taken

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### [Alkindi \(hydrocortisone granules\): risk of acute adrenal insufficiency in children when switching from hydrocortisone tablet formulations to granules](#)

18 February 2021

When children receiving replacement therapy for adrenal insufficiency are being switched from hydrocortisone tablets to Alkindi granules, parents or carers should be informed of the need to be extra vigilant for symptoms of adrenal insufficiency.

Proposed action

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



Action taken

Status	Action due date	Date completed
Unassigned		

### [Discontinuation Of Morphine Sulphate \(Mst Continus\) 20mg, 30mg, 60mg, 100mg And 200mg Prolonged Release Granules For Oral Suspension](#)

26 February 2021

All strengths of MST Continus® prolonged release granules for oral suspension are being permanently discontinued during 2021 due to difficulty sourcing a key excipient. Alternative morphine presentations, both prolonged release and immediate release, remain available and will be able to support increased demand. This alert contains further information and action for providers.

Proposed action

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



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Midlands and Lancashire  
Commissioning Support Unit

### Summary of Product Characteristics updates

#### Asmanex (mometasone furoate) Twisthaler 200 and 400 micrograms Inhalation Powder

SPC has been updated to advise that after each dose, patients should rinse their mouth with water and spit out the contents without swallowing.

#### Bydureon (exenatide) products

SPC updated to include addition of delayed gastric emptying as an uncommon side effect. This side effect has also been added to Byetta (exenatide) SPC's.

#### Depefex (venlafaxine hydrochloride) XL Capsules – all strengths

SPCs updated to include risk of serotonin syndrome especially if taken with other serotonergic agents; and that suicide/suicidal thoughts & aggression have been observed during changes in venlafaxine dosing regimen, including during discontinuation.

#### Duloxetine capsules

SPC updated to include caution in the elderly, risk of serotonin syndrome when using concomitantly with serotonergic agents and details a new potential adverse effect of treatment of postpartum haemorrhage (frequency unknown).

#### Eldepryl (selegiline hydrochloride) Tablets – all strengths

SPCs updated to include risk of serotonin syndrome with concomitant administration of selegiline hydrochloride and buprenorphine/opioids, which may result in a potentially life-threatening condition.

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### [Episenta \(sodium valproate\) 500 mg prolonged-release granules](#)

Update includes undesirable effects in the paediatric population, mainly severe liver damage under the age of 3 years. Pharmacokinetic data shows systemic clearance varies with age for below age 10 years. Ages up to 2 months have decreased clearance compared to adults.

### [Indivina \(medroxyprogesterone acetate/estradiol valerate\) tablets – all strengths](#)

Large meta-analysis showed that after stopping treatment, excess risk of breast cancer will decrease with time and time needed to return to baseline depends on duration of prior HRT use; when taken for more than 5 years, the risk may persist for 10 years or more.

### [Lamotrigine tablets](#)

Information on photosensitivity reactions has been added to the SPC. There have been reports of photosensitivity reactions associated with lamotrigine use. In several cases, the reaction occurred with a high dose (400mg or more), upon dose escalation or rapid up-titration.

### [Levosert \(levonorgestrel\) 20 micrograms/24 hours Intrauterine Delivery System](#)

This educational brochure is intended to minimise the risk of medication errors due to confusion between Levosert and other available levonorgestrel containing intrauterine delivery system and to provide information on the risk of ectopic pregnancies.

### [Neupro \(rotigotine\) transdermal patch – all strengths](#)

Special warnings and precautions for use section of SPC updated to include information on symptoms of dopamine agonist withdrawal syndrome and reference to dopamine dysregulation syndrome, a potential adverse effect of treatment.

### [Ozempic \(semaglutide\) solution for injection in pre-filled pen](#)

The SPC has been updated to incorporate information from a study of semaglutide as add-on to SGLT2 inhibitor treatment (SUSTAIN 9), including efficacy results and safety (rates of hypoglycaemia and gastrointestinal adverse events).

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### Plavix (clopidogrel) 300 mg film-coated tablets

SPC have been updated with licence extension for use in combination with aspirin in adult patients with moderate to high-risk transient ischaemic attack (ABCD2-[1] score  $\geq 4$ ) or minor ischaemic stroke (NIHSS-[2]  $\leq 3$ ) within 24 hours of an event.

### Salofalk (mesalazine) – all products

Stevens-Johnson syndrome and toxic epidermal necrolysis added as adverse effects of treatment with a frequency unknown.

### Sertraline tablets

SPC updated to include information on the risk of developing Serotonin Syndrome or Neuroleptic Malignant Syndrome, including increased risk where there is concomitant use with other serotonergic medicines.

### Teragezza (Co-cyprindiol)

Materials include a checklist for prescribers, important information for women regarding the risk of thromboembolism, and a patient alert card advising women of this risk, the signs and symptoms to look out for, and what action to take.

### Venlafaxine Tablets

SPC details a new potential adverse effect of treatment of postpartum haemorrhage (frequency unknown).

### ViePax XL 225 mg Prolonged-Release Tablets

SPC now notes that observational data indicate an increased risk of postpartum haemorrhage following SSRI/SNRI exposure within the month prior to birth. Manufacturers advise it must only be given in pregnancy if the expected benefits outweigh any possible risk.

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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### Xarelto (rivaroxaban) film-coated tablets – all strengths

SPC updated with license extension for the treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing from 30 kg to 50 kg after at least 5 days of initial parenteral anticoagulation treatment.