

## Medicines Safety Assurance Tool

December 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)

### Systemic and inhaled fluoroquinolones: small risk of heart valve regurgitation; consider other therapeutic options first in patients at risk

18 December 2020

Fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients at risk for heart valve regurgitation (incompetence).

Proposed action

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



[Redacted area]

Action taken

[Redacted area]

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

### Erythromycin: caution required due to cardiac risks (QT interval prolongation); drug interaction with rivaroxaban

18 December 2020

Erythromycin has been associated with events secondary to QT interval prolongation such as cardiac arrest and ventricular fibrillation. Erythromycin should not be given to patients with a history of QT interval prolongation or ventricular cardiac arrhythmia, including torsades de pointes, or patients with electrolyte disturbances.

Proposed action

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



[Redacted area]

Action taken

[Redacted area]

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

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Midlands and Lancashire  
Commissioning Support Unit

### [Erythromycin: update on known risk of infantile hypertrophic pyloric stenosis](#)

18 December 2020

Updates have been made to the magnitude of the known risk of infantile hypertrophic pyloric stenosis following exposure to erythromycin in infancy as a result of new epidemiological data.

Proposed action

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



Action taken

Status

Action due date

Date completed

### [Letter sent to Healthcare Professionals: Midazolam maleate \(Epistatus 10mg in 1ml oromucosal soln, multidose bottle\)](#)

21 December 2020

Letter advises of reports of unsecured bottle tops which can be removed without unscrewing. Consequences include evaporation of ethanol and subsequent crystallisation which may reduce concentration of midazolam. Bottles should be checked for secure caps and presence of crystals.

Proposed action

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 Practice audit/search  Other (please specify)



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### Summary of Product Characteristics updates

December 2020

#### Actiq (fentanyl) Lozenges

Sleep apnoea syndrome has been added as a potential adverse effect of treatment (frequency unknown). SPC advises that opioid use increases the risk of central sleep apnoea (CSA) in a dose-dependent fashion. In patients who present with CSA, consider decreasing the opioid dose.

#### Crinone 8% Progesterone Vaginal Gel

Headache, somnolence, abdominal pain have been removed as common side effects and SPC now states Crinone has no influence on the ability to drive and use machines.

#### Dermovate (Clobetasol propionate) products

Central serous chorioretinopathy has been added as a very rare adverse reaction, reported after use of systemic and topical corticosteroids.

#### Estradot transdermal patches

The SPC has been updated regarding the risk of breast cancer, following the PRAC signal recommendation for HRT medicinal products.

#### Lyrica (pregabalin) - all products

SPC updated to warn of reports of severe respiratory depression in relation to pregabalin use; dose adjustments may be necessary in at risk patients (e.g. compromised respiratory function, respiratory or neurological disease, renal impairment, on CNS depressants and elderly).

Proposed action

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



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### Maxtrex (methotrexate) 2.5 and 10 mg Tablets

Skin exfoliation, dermatitis exfoliative, paraesthesia, hypoaesthesia and oedema have been added to SPC as adverse effects.

### Oruvail (ketoprofen) Prolonged-Release Hard Capsules – all strengths

SPC updated to warn ketoprofen can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection.

### Vimpat (lacosamide) – all products

SPCs revised to include license extension as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients with idiopathic generalized epilepsy aged 4 years and older.

### Zithromax (azithromycin dehydrate) – all products

SPCs updated to advise that limited published literature indicates azithromycin is present in human milk at an estimated highest median daily dose of 0.1 to 0.7 mg/kg/day; and no serious adverse effects of azithromycin on breast-fed infants were observed.

### Zydol XL (tramadol) prolonged-release Tablets

SPC updated to note tramadol should be used with caution in patients with intracranial lesions, reduced level of consciousness of uncertain origin, and constipation. Information on concomitant use with sedative medicines and on influence of opioids on the HPA axis has been added.