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## Medicines Safety Assurance Tool November 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

### Coroner writes to NICE over lack of prescribing guidance for amitriptyline and oxycodone

*Pharmaceutical Journal*

A coroner's letter, following the death of a patient who was prescribed amitriptyline and oxycodone, has criticised the BNF for its lack of guidance on co-prescribing this combination, and highlights the need for both caution and monitoring.

<https://www.pharmaceutical-journal.com/news-and-analysis/news-in-brief/coroner-writes-to-nice-over-lack-of-prescribing-guidance-for-amitriptyline-and-oxycodone/20207389.article>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

### Dangers of selective NSAID prescribing in Quality and Outcomes Framework

*British Medical Journal*

Letter warns that while coxibs are less likely to cause GI bleeds, they are prothrombotic and thus carry higher risk of CV events. Patients who might require NSAIDs may also be at risk of both GI bleeds and CVD (e.g. frail, elderly, multimorbidity, polypharmacy, smokers).

<https://www.bmj.com/content/367/bmj.l6697>

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

### Cellcept (mycophenolate mofetil) 500mg Film-Coated Tablets

SPC now warns that CellCept has a moderate influence on the ability to drive and use machines. It also now states that no data are available for treatment of first or refractory rejection in paediatric transplant patients.

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

### Dapagliflozin (Forxiga), educational risk minimisation materials

AstraZeneca UK Limited

Guide is now available for healthcare professionals and one for people with type 1 diabetes mellitus and their carers to minimise the risk of Diabetic Ketoacidosis (DKA).

<https://www.medicines.org.uk/emc/product/2865/rmms>

### Desitrend (levetiracetam) – all products

Delirium and encephalopathy added to SPC as rare ( $\geq 1/10,000$  to  $< 1/1,000$ ) undesirable effects of treatment.

<https://www.medicines.org.uk/emc/product/2883/smpc>

### Glycopyrronium bromide (Sialanar) 320 micrograms /ml Oral Solution, educational risk minimisation materials

Proveca Limited

These educational materials focus on provision of advice for recognition of anticholinergic effects that can be associated with glycopyrronium bromide containing products and how best to manage specific events.

<https://www.medicines.org.uk/emc/product/2301/rmms>

### Lustral (sertraline) 50 and 100mg film coated tablets

Warning added advising that SSRIs may cause symptoms of sexual dysfunction, and there been reports the symptoms have continued despite discontinuation of treatment. Maculopathy has been added to SPC as an adverse effect.

<https://www.medicines.org.uk/emc/product/1070/smpc>

### Octasa (mesalazine) modified release tablets – all strengths

Nephrolithiasis (kidney stones) added as an undesirable effect of treatment with unknown frequency to the SPC.

<https://www.medicines.org.uk/emc/product/2827/smpc>

### Qvar (beclometasone dipropionate) MDI – all strengths

The SPC has been updated with prescribing information in relation to treatment of children aged 5 years and above.

<https://www.medicines.org.uk/emc/product/604/smpc>

### Salofalk (mesalazine) gastro-resistant prolonged-release granules and tablets

Sections 4.4 and 4.8 of the SPC has been revised to advise cases of nephrolithiasis have been reported with the use of mesalazine including stones with a 100% mesalazine content. Adequate fluid intake during treatment should be advised.

<https://www.medicines.org.uk/emc/product/139/smpc>

Proposed action

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

Action taken

Status

Unassigned

Action due date

Date completed

**Singulair (montelukast sodium – all products)**

SPC revised to inform neuropsychiatric events have been reported in adults, adolescents, and children taking Singulair. Obsessive-compulsive symptoms and dysphemia have also been added as very rare adverse effects of treatment (<1/10,000 people).

<https://www.medicines.org.uk/emc/product/198/smpc>

**Steglatro (ertugliflozin) tablets**

SPC now advises that treatment should be interrupted in patients who are hospitalised for major surgical procedures or acute serious medical illnesses and that monitoring of ketones is recommended. Treatment can be resumed when the patient's condition has stabilised.

<https://www.medicines.org.uk/emc/product/10099/smpc>