

Medicines Safety Assurance Tool

December 2019

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Midlands and Lancashire
Commissioning Support Unit

[Domperidone for nausea and vomiting: lack of efficacy in children; reminder of contraindications in adults and adolescents](#)

16 Dec 2019

Domperidone is no longer licensed for use in children younger than 12 years or those weighing less than 35 kg. Results from a placebo-controlled study in children younger than 12 years with acute gastroenteritis did not show any difference in efficacy at relieving nausea and vomiting compared with placebo.

Proposed action

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

Action taken

Status	Action due date	Date completed
Unassigned ▼		

Summary of Product Characteristics updates

[Brufen \(ibuprofen\) tablets \(all strengths\)](#)

SPCs now warn skin reactions, some fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely with use of NSAIDs. Treatment should be stopped at first appearance of skin rash/mucosal lesions/ hypersensitivity.

[Femara \(letrozole\)](#)

SPC updated with warnings about the risk of tendonitis and tendon rupture, as per PRAC recommendation.

[Lopid \(gemfibrozil\) 300 mg Hard Capsules](#)

SPC updated to warn that co-administration of with selexipag, a substrate for CYP2C8, doubled exposure (AUC) to selexipag and increased exposure to active metabolite by~ 11-fold. Concomitant administration of gemfibrozil with selexipag is thus contraindicated.

Proposed action

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

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Omacor (omega-3-acid ethyl esters) 1000 mg Soft Capsules

Post-myocardial infarction indication has been removed from SPC. Omacor remains licensed for treatment of hypertriglyceridaemia.

Pentasa (mesalazine) Sachets- all strengths

SPCs have been updated to advise on another method of administration in which the entire content of the sachet can be taken with yogurt and consumed immediately.

Plavix (clopidogrel) 75 and 300 mg film-coated tablets

SPC now warns that as with other oral P2Y12 inhibitors, co-administration of opioid agonists has potential to delay and reduce absorption of clopidogrel, presumably because of slowed gastric emptying. The clinical relevance is unknown.

Stemetil (prochlorperazine) products

SPC updated to include warning about co-administration of phenothiazines with amitriptyline/amitriptylinoxide (AA), a CYP2D6 substrate that may lead to increase in plasma levels of the latter. Patients should be monitored for dose-dependent adverse reactions associated with AA.

Timoptol (timolol) preparations

Hallucination has been added as a potential adverse effect of treatment to the SPC.

Toujeo 300 units/ml DoubleStar and SoloStar (insulin glargine), solution for injection in a pre-filled pen

The SPCs have been updated to include information about the license extension to include use in children from the age of 6 years.

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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About this document

MLCSU collates and shares the latest current awareness and evidence-based medicines information from NICE and UKMi relating to medicines safety each month.

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