

Medicines Safety Assurance Tool

April 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

[Polyethylene glycol \(PEG\) laxatives and starch-based thickeners: potential interactive effect when mixed, leading to an increased risk of aspiration](#)

27 April 2021

Addition of a polyethylene glycol (PEG)-based laxative to a liquid that has been thickened with a starch-based thickener may counteract the thickening action, placing patients with dysphagia at a greater risk of aspiration.

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]

[Using chloramphenicol eye drops in children under 2 years](#)

29 April 2021

The SPS website now features a webpage signposting information on this issue, which currently includes regulatory advice from the European Medicines Agency and clinical advice from the Royal College of Ophthalmologists.

Proposed action

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



[Redacted area]

Action taken

[Redacted area]

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Summary of Product Characteristics updates

Celebrex (celecoxib) capsules

The SPC has been updated to warn that Celebrex may have minor influence on driving and use of machines.

Cellcept (mycophenolate mofetil) preparations

SPC updated to note that mycophenolic acid has a cytostatic effect on B- and T-lymphocytes, therefore an increased severity of COVID-19 may occur. Dose reduction or discontinuation should be considered for patients in cases of clinically significant COVID-19.

Frisium (clobazam) 10mg Tablets

SPC warns some epidemiological studies suggest an increased incidence of suicidal ideation, suicide attempt and suicide in patients with or without depression and treated with benzodiazepines and other hypnotics, including clobazam; a causal relationship has not been established.

Coversyl arginine plus (indapamide and perindopril) film-coated tablets

Rhabdomyolysis and muscle disorders have been added as potential adverse effects of treatment (frequency unknown).

Eliquis (apixaban) tablets – all strengths

SPC includes erythema multiforme as an adverse drug reaction. Frequency is very rare for prevention of stroke and systemic embolism in adults with non-valvular atrial fibrillation, and unknown for treatment/prevention of deep vein thromboembolism and pulmonary embolism.

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Elvans (lisdexamphetamine) hard capsules

SPC updated with data from two cohort studies of pregnancies with exposure to amphetamine. One study does not suggest an increased risk of congenital malformations and one study suggests an increased risk of preeclampsia and preterm birth.

Ikorel (nicorandil) 10 and 20 mg Tablets

Third and sixth nerve paralysis (often associated with headache) have been added to SPC as adverse effect of unknown frequency.

Indivina (estradiol valerate and medroxyprogesterone acetate) tablets

Exacerbation of angioedema has been added as a potential adverse effect of treatment (frequency unknown), and caution is recommended in patients with a history of angioedema. SPC also notes many HIV/HCV antivirals can increase or decrease plasma concentrations of oestrogen.

Innozide (enalapril maleate and hydrochlorothiazide) tablets

Choroidal effusion has been added as a potential adverse effect of treatment (frequency unknown). Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of initiation. Treatment should be discontinued promptly.

Jinarc (tolvaptan) tablets

Dysgeusia, syncope, dry skin, urticaria, arthralgia, myalgia and weight gain have been added to the SPC as common adverse events.

Lopid (gemfibrozil) film-coated tablets

SPC updated to note concomitant use with rosuvastatin at 40mg is contraindicated; concomitant use with lower doses of atorvastatin should only be used when the benefit outweighs the risks.

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Natrilix (indapamide) tablets

SPC updated to note cases of rhabdomyolysis have been reported, mainly in context of severe hypokalaemia, and that sulfonamide drugs can cause an idiosyncratic reaction resulting in choroidal effusion with visual field defect, transient myopia, and acute angle-closure glaucoma.

Nurofen (ibuprofen) Meltlets 200mg Orodispersible Tablets

SPC updated to note acute generalised exanthematous pustulosis has been reported in relation to ibuprofen-containing products. Ibuprofen should be discontinued at the first appearance of signs and symptoms of severe skin reactions.

Sporanox (itraconazole) oral suspension

SPC now notes that in cystic fibrosis patients, variability in plasma levels of itraconazole leading to subtherapeutic concentrations has been observed. If no response to oral solution, consideration should be given to switching to itraconazole IV or to alternative therapy.

Vipdomet 12.5 mg/1000 mg (alogliptin/metformin) film coated tablets

SPC updated to warn that there have been post-marketing reports of bullous pemphigoid in patients taking DPP-4 inhibitors including alogliptin. If bullous pemphigoid is suspected, alogliptin should be discontinued. Also interstitial nephritis added as ADR of unknown frequency.