

Medicines Safety Assurance Tool

December 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



Midlands and Lancashire
Commissioning Support Unit

Haloperidol (Haldol): reminder of risks when used in elderly patients for the acute treatment of delirium

10 December 2021

We remind healthcare professionals that elderly patients are at an increased risk of adverse neurological and cardiac effects when being treated with haloperidol for delirium. The lowest possible dose of haloperidol should be used for the shortest possible time, and cardiac and extrapyramidal adverse effects should be closely monitored.

Proposed action

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



Action taken

Status	Action due date	Date completed

Dapagliflozin (Forxiga): no longer authorised for treatment of type 1 diabetes mellitus

10 December 2021

The authorisation holder for dapagliflozin has withdrawn the indication for type 1 diabetes mellitus. The removal of the type 1 diabetes indication is not due to any new safety concerns and the other indications of dapagliflozin are unchanged.

Proposed action

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



Action taken

Status	Action due date	Date completed

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[NPPG Position statement 2021-02: Use of Steroid Medication Warning Cards for Children and Young People](#)

10 December 2021

This position statement produced with input from the British society of Paediatric Endocrinology and diabetes provides clear guidance on the two different steroid cards that are available for use of children and young people and when each of these cards should be issued.

Proposed action

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



Action taken

Status

Action due date

Date completed

Summary of Product Characteristics updates

[BuTrans \(buprenorphine\) 15 microgram/hour transdermal patch](#)

Updates include addition of adverse effects hyperalgesia and drug tolerance, warning statements regarding respiratory depression, tolerance, opioid use disorder, withdrawal, skin reactions and sleep apnoea, and updated information on titration and application.

[Curatoderm \(tacalcitol monohydrate\) 4 micrograms/g Lotion](#)

SPC updated with addition of contraindications; psoriasis punctata or psoriasis pustulosa, pregnancy & lactation and patients with severe hepatic, renal or heart disease (as there is no experience).

Proposed action

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



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Duodopa (levodopa-carbidopa) intestinal gel

New materials include a patient pocket guide, providing a practical overview of the system and potential complications, and training for AbbVie Duodopa Specialists on the system, PEG-J placement, aftercare and minimisation of procedure complications.

E45 Cream

The SPC has been updated to note that the product should not be applied to the mucous membranes or to broken skin.

Invokana (canagliflozin) tablets

SPC notes, for treatment of diabetic kidney disease, there are data for use in patients with eGFR ≥ 30 mL/min, and that patients with albuminuria may experience more benefit than those without. Dosing for patients with eGFR between 30 and 60 mL/min is 100mg once daily.

Lamictal (lamotrigine) Tablets

SPC updated to add paracetamol to list of medicines that have little or no effect on lamotrigine concentration, and to note paracetamol (1g QDS) reduced the plasma AUC and C_{min} of lamotrigine by an average of 20% and 25%, respectively, in a study in healthy adult volunteers.

Lemsip Max (paracetamol, guaifenesin, phenylephrine) preparations

SPCs updated to note the product should not be used in children aged under 16 years of age (previously 12), and that concomitant use of other sympathomimetic decongestants is contraindicated.

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Maxtrex (methotrexate) 2.5 and 10 mg Tablets

SPC updated with addition of warning about progressive multifocal leukoencephalopathy (PML) in line with PRAC recommended text.

Mercilon Tablets (desogestrel and ethinylestradiol)

SPC updated to note concomitant use with glecaprevir/pibrentasvir is contraindicated, as this may increase the risk of ALT elevations. Users of Mercilon must switch to an alternative method of contraception prior to starting therapy with this combination drug regimen.

Methylphenidate products

This website, a collaboration of methylphenidate Marketing Authorisation Holders in the EU, hosts materials for physicians to support appropriate prescribing of methylphenidate, including monitoring checklists and a chart for ongoing monitoring.

Metobject (methotrexate) pre-filled pens

SPC notes cases of progressive multifocal leukoencephalopathy have been reported, mostly in combination with other immunosuppressive medication. It can be fatal and should be considered in the differential diagnosis in patients with new onset or worsening neurological symptoms.

Neutrogena T/Gel (coal tar extract) Therapeutic Shampoo

SPC now warns shampoo contains esters of benzoic acid and benzyl benzoate which can mildly irritate skin, eyes and mucous membranes, and butylated hydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis) as well as irritation to eyes and mucous membranes.

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Olsalazine Sodium 500 mg Tablets

SPC now notes treatment should only be initiated in patients with renal impairment if the benefits are considered to outweigh risk. In addition, periodic renal function monitoring, especially in the early months of treatment, should be conducted based on clinical judgment.

Prefibin (buprenorphine) 8 mg Sublingual Tablets

SPC updated to note opioids can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. In patients who present with CSA, consider decreasing the total opioid dose.

Trifluoperazine 5mg/5ml Oral Solution

Retinopathy has been added as a very rare potential adverse effect of treatment.

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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