

Medicines Safety Assurance Tool

November 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

Adrenaline auto-injectors: reminder for prescribers to support safe and effective use

16 November 2021

Emerade 300 and 500 microgram adrenaline auto-injectors have been re-supplied to the market following the implementation of corrective actions – patients and their caregivers should be provided with training and advice specific to their prescribed adrenaline auto-injector. Follow the advice in the Summary of Product Characteristics for dosing considerations and continue to reiterate to patients the importance of carrying 2 in-date adrenaline auto-injectors with them at all times.

Proposed action

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



Action taken

Status	Action due date	Date completed

Topical corticosteroid withdrawal reactions

29 November 2021

Summary and context are provided for the recent MHRA Drug Safety Alert reminding healthcare professionals that withdrawal reactions can occur after stopping long-term use of topical corticosteroids. Those on long term treatment should have a treatment review.

Proposed action

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



Action taken

Status	Action due date	Date completed

Medicines Safety Assurance Tool

November 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

Summary of Product Characteristics updates

Addepta (methylphenidate) XL modified-release hard capsules – all strengths

Documents provided for supporting healthcare professionals include an ADHD introduction document to use as a guide for prescribing, a chart for ongoing monitoring including recordings of observations, and two separate checklists for treatment initiation and ongoing monitoring.

Benilexa One Handed (levonorgestrel) 20 micrograms/24 hours Intrauterine Delivery System

This patient alert card is intended to be used for, date of insertion and removal, date of next appointments & batch number. A Healthcare professional guide is provided to minimise risk of application errors and ectopic pregnancies.

Briviact (brivaracetam) - all presentations

Updated with following ADRs reported after overdose: nausea, vertigo, balance disorder, anxiety, fatigue, irritability, aggression, insomnia, depression, & suicidal ideation in post-marketing experience, which in general, were consistent with the known adverse reactions.

DuoResp Spiromax 160/4.5 and 320/9.0 (budesonide/formoterol) micrograms inhalation powder

Updated to reflect licence extension covering use in adolescent patients (12 years and above) for the treatment of asthma.

Proposed action

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



Action taken

Status

Action due date

Date completed

Medicines Safety Assurance Tool

November 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

[Eloine \(ethinylestradiol 0.020mg and drospirenone 3mg\) film coated tablets](#)

Updated SPC notes concomitant use with glecaprevir/pibrentasvir is contraindicated owing to increased risk of ALT elevation.

[EVRA \(norelgestromin and ethinyl estradiol\) 203 micrograms and 33.9 micrograms/24 hours transdermal patch](#)

Materials provided include a prescriber checklist; to be used in conjunction with the detail in the SPC, a combined hormonal contraceptive user card highlighting risks of blood clots and a patient information leaflet that can be provided to the patient by the prescriber.

[Galenphol \(pholcodeine\) Strong Linctus](#)

SPC notes severe cutaneous adverse reactions including acute generalized exanthematous pustulosis, which can be fatal, are potential adverse effects of treatment (frequency unknown). If signs and symptoms appear treatment should be withdrawn immediately.

[Forxiga \(dapagliflozin\) tablets](#)

SPC has been updated to remove the type 1 diabetes mellitus (T1DM) indication. Manufacturers report that the withdrawal of this indication is not due to new safety concerns, but notes that diabetic ketoacidosis is a known and common side effect when used in T1DM.

[Lariam \(mefloquine\) 250 mg tablets](#)

Documents provided include; 'Checklist for Healthcare Professionals', 'Guide for Healthcare Professionals' & 'Patient Alert Card'. A letter to healthcare professionals is also provided with a reminder of the neuropsychiatric adverse reactions risks with malaria chemoprophylaxis.

Medicines Safety Assurance Tool

November 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

[NatriliX SR \(indapamide\) Tablets](#)

Various updates include addition of erectile dysfunction (uncommon), hypochloraemia (rare) and hypomagnesaemia (rare) as adverse reactions, an increase in frequency of hypokalaemia to 'common', and to note monitoring of magnesium is recommended in those on digitalis preparations.

[Nicotinell TTS \(nicotine\) Transdermal Patches](#)

New information added to SPC, including on use in pregnancy and during breast-feeding, advice on use and monitoring in patients with a history of dermatitis, seizures and diabetes mellitus, and advice on administration.

[Nurofen Cold & Flu Relief \(ibuprofen; phenylephrine\) 200mg/5mg Tablets](#)

SPC updated to note that phenylephrine should not be used in patients with pheochromocytoma.

[PecFent \(fentanyl\) nasal spray, solution](#)

SPC updated to note concomitant use of medicinal products containing sodium oxybate and fentanyl is contraindicated, and that concomitant use with sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma and death.

[Prograf \(tacrolimus\) hard capsules and concentrate for solution for infusion](#)

SPC updated to include new information on interaction with CYP3A4 inhibitors/inducers, information on nephrotoxicity and instruction to avoid concurrent use with drugs with nephrotoxic effects, and the new adverse reaction 'Posterior reversible encephalopathy syndrome'.

Medicines Safety Assurance Tool

November 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

[Tephine \(buprenorphine\) 400 microgram sublingual tablets](#)

SPC now notes that 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.

[Yasmin \(ethinylestradiol 0.030mg and drospirenone 3mg\) film-coated tablets](#)

Updated SPC notes concomitant use with glecaprevir/pibrentasvir is contraindicated owing to increased risk of ALT elevation.

[Zonegran \(zonisamide\) 50 mg hard capsules](#)

The fertility, pregnancy and lactation and the preclinical safety data sections have been updated following the completion of the MHRA's review of the safety of use during pregnancy of anti-epileptic medicines, including zonisamide.

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.

© NICE 2021. All rights reserved. Subject to [Notice of rights](#).

NICE guidance is prepared for the National Health Service in England. All NICE guidance is subject to regular review and may be updated or withdrawn. NICE accepts no responsibility for the use of its content in this product/publication.