

Medicines Safety Assurance Tool

August 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

Maxtrex (methotrexate)

06 August 2021

The healthcare professionals guide contains information on how to minimise risk of overdose from patients incorrectly taking methotrexate daily instead of weekly for autoimmune diseases. Patients should be advised to write treatment day on the accompanying Patient Reminder Card.

Proposed action

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



Action taken

Status

Action due date

Date completed

Safety of medicines in porphyria

09 August 2021

This series of articles describes the different types of porphyria. Some medicines can precipitate a painful acute attack and this resource aims to help clinicians making safer medicine choices for individuals with this condition.

Proposed action

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



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Clexane® (enoxaparin sodium) device – Important Information regarding differences between PREVENTIS and ERIS needle guard safety systems

13 August 2021

From August 2021, Clexane pre-filled syringes with both ERIS and PREVENTIS safety systems will be in the supply chain simultaneously. This healthcare professional communication highlights the differences in the needle guard safety systems between the two devices.

Proposed action

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



Action taken

Status

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Date completed

Potent Synthetic Opioids Implicated In Increase In Drug Overdoses

18 August 2021

In past 2 weeks there have been unprecedented number of overdoses (some deaths) in drug users, primarily of heroin, in some parts of country. Testing in 3 cases indicate adulteration with isotonitazene, a potent synthetic opioid. Alert contains urgent actions for providers.

Proposed action

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



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Summary of Product Characteristics updates

All valproate semisodium, sodium valproate or valproic acid products

SPC updated to include contraindication of hypersensitivity to valproate semisodium or any other excipients listed and ophthalmoplegia has been added as another symptom of a POLG-related disorder, which is a contraindication to use.

Actiq (fentanyl citrate) Lozenges- all strengths

Now contraindicated in patients on sodium oxybate products; new section added on risk of opioid use disorder as well as advice on regular dental visits as ACTIQ contains ~ 2 grams of sugar, which increases risk of dental decay. Bleeding at site of application added as side effect.

Co-trimoxazole tablets

SPC now warns severe cases of respiratory toxicity, including potential progression to Acute Respiratory Distress Syndrome, have been reported (very rare). If suspected co-trimoxazole should be discontinued and appropriate treatment given.

Crestor (rosuvastatin) all strength film-coated tablets

SPC now highlights severe cutaneous adverse reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) is a potential adverse effect of treatment. If signs occur, treatment should be discontinued immediately.

Diflucan (fluconazole) capsules and powder for oral solution – all strengths

SPC updated to include drug reaction with eosinophilia and systemic symptoms (DRESS) of unknown frequency, data when treated with a cumulative dose of ≤ 150 mg in the first trimester of pregnancy and information about superinfection with Candida species.

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Emerade (adrenaline tartrate) 500 micrograms, solution for injection in pre-filled pen

Method of instruction has been updated to state a second injection should be administered if the patient still feels unwell and SPC now states any nonfunctioning pens should be retained for investigation.

Episenta (sodium valproate) solution for injection and prolonged release granules – all strengths

SPC updated to include interaction with metamizole, an inducer of CYP2B6 and CYP3A4, which may cause a reduction in plasma concentrations of valproate with potential decrease in clinical efficacy. Clinical response and/or drug levels should be monitored as appropriate.

Forxiga (dapagliflozin) 5 and 10 mg film-coated tablets

SPC has been updated with new indication of treatment of adults with chronic kidney disease and supporting data from the Dapa CKD study, as well as statement that overall safety profile in this population was consistent with the known safety profile of dapagliflozin.

Innovace (enalapril) Tablets- all strengths

SPC updated to include contraindication of concomitant use with sacubitril/valsartan. Hypersensitivity/angioneurotic oedema and hyperkalaemia warnings updated in relation to use of ACE inhibitors.

Otrivine (xylometazoline) Nasal products

Epistaxis has been added to SPC as an uncommon adverse effect.

Sabril (vigabatrin) tablets

SPN now notes cases of intramyelinic oedema (IME) have been reported, particularly in infants treated for infantile spasms. It is recommended to progressively discontinue vigabatrin when IME is observed.

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Topical steroid products

SPC notes that with long term continuous use of topical steroids, a severe form of rebound flare can develop (dermatitis with intense redness, stinging and burning). After resolution, reapplication should be undertaken with caution and specialist advice is recommended.

Vitamin E Suspension 100mg/ml (Alliance)

SPC updated to note it contains benzoic acid (may increase jaundice in newborns), polyoxyl castor oil (may cause stomach upsets/diarrhoea), propylene glycol (co-administration with any substrate for alcohol dehydrogenase may induce serious adverse effects in neonates) and sucrose.

Xarelto (rivaroxaban) 1mg/ml granules for oral suspension and film coated tablets – all strengths

SPC updated to include warning that patients with cancer may be at higher risk of bleeding and thrombosis and the individual benefit should be weighed against risk for bleeding in patients with active cancer dependent on tumour location, antineoplastic therapy & stage of disease.