

Medicines Safety Assurance Tool

October 2020

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

Warfarin and other anticoagulants – monitoring of patients during the COVID-19 pandemic

14 October 2020

MHRA has published guidance following concerns over an apparent increase in the number of patients taking warfarin found to have elevated INR values during the pandemic; and reminds healthcare professionals and patients that continued close INR monitoring is crucial.

Proposed action

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



[Redacted content]

Action taken

[Redacted content]

Status	Action due date	Date completed
Unassigned		

DTB Select: Steroid emergency cards - action needed

21 October 2020

Article summarises the actions for organisations to take to implement the new steroid emergency card following a safety alert. The new card features aims to help healthcare staff identify adult patients with adrenal insufficiency and give emergency treatment for adrenal crisis.

Proposed action

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



[Redacted content]

Action taken

[Redacted content]

Status	Action due date	Date completed

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Summary of Product Characteristics updates

Abilify (aripiprazole) preparations

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been added as an adverse drug reaction (frequency not known).

Ciprallex (escitalopram) film-coated tablets

SPC now states that co-administration with hydroxyzine is contra-indicated owing to a potential additive risk of QT interval prolongation.

Concerta (methylphenidate) XL prolonged release tablets- all strengths

Dysphemia, a speech disorder characterised by stammering or stuttering, has been added to SPCs as an adverse effect of unknown frequency.

Constella (linaclotide) 290 micrograms hard capsules

SPC revised to advise breastfeeding is not expected to result in exposure of the infant to linaclotide and thus it can be used during breast-feeding.

Cordarone (amiodarone) X 200 mg Tablets

SPC now notes co-administration of amiodarone with sofosbuvir-containing regimens may lead to serious symptomatic bradycardia. Amiodarone should only be used in patients on sofosbuvir-containing regimens when alternative treatments are not tolerated/contraindicated.

Enstilar (calcipotriol/betamethasone) Cutaneous Foam

SPC now advises those who responded to 4 weeks' of once daily treatment are suitable for long-term maintenance treatment involving twice weekly application on 2 non-consecutive days to previously affected areas; and between applications there should be 2-3 days without treatment.

Proposed action

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



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Exocin (ofloxacin) 3 mg/ml Eye Drops

SPC warns that the preservative, benzalkonium chloride, may cause symptoms of dry eyes, and may affect the tear film and corneal surface. Caution is required in dry eyes and where the cornea may be compromised. Patients should be monitored in case of prolonged use.

Fobumix (budesonide, formoterol fumarate dehydrate) Easyhaler – all products

Dysphonia (abnormal voice) including hoarseness has been added to SPC as a common ($\geq 1/100$ to $< 1/10$) adverse drug reaction of treatment.

Fragmin (dalteparin) solution for injection

The SPCs for all Fragmin prefilled syringes have been updated to note that their needle shield may contain latex (natural rubber) which may cause severe allergic reactions in individuals with hypersensitivity to latex (natural rubber) [previously latex-free].

Humulin (human insulin) products

SPCs now advise that patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis, which can lead to potential risk of delayed insulin absorption and worsened glycaemic control.

Imigran (sumatriptan) preparations

Dysphagia has been added as a potential adverse effect of treatment (frequency unknown).

Jardiance (empagliflozin) film-coated tablets

SPC has been updated to note that it should not be used for treatment of patients with type 1 diabetes, with clinical trial data showing its use as an adjunct to insulin was associated with increased diabetic ketoacidosis occurrence with common frequency compared to placebo.

Keppra (levetiracetam) products

Rare cases of ECG QT interval prolongation have been observed, so it should be used with caution in those: 1) with QTc-interval prolongation, 2) concomitantly treated with drugs affecting QTc-interval, or 3) with relevant pre-existing cardiac disease or electrolyte disturbances.

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Lustral (sertraline hydrochloride) coated tablets – all strengths

SPCs updated to include microscopic colitis (inflammation of the large intestine) as an adverse event of treatment of unknown frequency.

Motilium (domperidone) 10mg Film-coated Tablets

SPC revised in line with MHRA advice issued in December to state that efficacy in children less than 12 years of age and in adolescents 12 years of age and older and weighing less than 35 kg has not been established.

OxyContin (oxycodone) prolonged release tablets

Various changes include updated warnings regarding concomitant use with benzodiazepines, addition of a warning regarding use of MAOIs within the previous 2 weeks, and the addition of sleep apnoea syndrome as a possible side effect.

OxyNorm (oxycodone) solution for injection or infusion

Sleep apnoea syndrome has been added as a potential adverse effect of treatment (frequency unknown). The SPC also notes that opioids may also cause worsening of pre-existing sleep apnoea.

Plenachol D3 Capsules (colecalfiferol; cholecalciferol)

The SPC has been updated to note that this product is now also licensed for use as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

Ranexa (ranolazine) prolonged-release Tablets- all strengths

Myoclonus has been added to SPC as an adverse event of unknown frequency. The SPC has also been updated to advise that in postmarketing experience, there have been reports of intentional overdose of ranolazine alone or in combination with other drugs with a fatal outcome.

Sevodyne (buprenorphine) transdermal patch

SPC now warns of risk of serotonin syndromewhen co-administered with other serotonergic agents, e.g. MAO inhibitors, SSRIs, SNRIs or tricyclic antidepressants. If co-administration is warranted, careful observation is advised, especially during initiation and dose increases.

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Testim (testosterone) 50 mg Transdermal Gel

SPC advises caution in pts with thrombophilia, or risk factors for venous thromboembolism (VTE). In thrombophilic pts; VTE cases have been reported even under anticoagulation treatment, therefore continuing testosterone treatment after first VTE event should be evaluated.

Transtec (buprenorphine) transdermal patch- all strengths

Following PRAC recommendation, SPCs now include warning that concomitant administration with other serotonergic agents, such SSRIs, SNRIs) or tricyclic antidepressants may result in serotonin syndrome, a potentially life-threatening condition.