Medicines Safety Assurance Tool

March 2021

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NHS Midlands and Lancashire Commissioning Support Unit

Guidance on issuing the Steroid Emergency Card

02 March 2021

The Society for Endocrinology, Specialist Pharmacy Service (SPS) and the British Association of Dermatology has produced more detailed guidance for use by primary and secondary care providers as necessary to implement the National Patient Safety Alert in a more consistent way.

Proposed action

Action taken

Status | Action due date | Date completed

How to minimise the risks of medication errors with rivastigmine patches

31 March 2021

This updated Q&A aims to raise awareness on the types of medication errors reported with rivastigmine patches, as well as highlighting strategies to improve medication safety on the prescribing and administration of these patches.

Proposed action

Action taken

Status | Action due date | Date completed

Summary of Product Characteristics updates

March 2021

Proposed action

Action taken

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Betamethasone dipropionate and calcipotriol (Enstilar) cutaneous foam

Update includes deletion of warning regarding UV exposure in section 4.4, deletion of statement regarding photocarcinogenicity studies in section 5.3, rewording of statement regarding dermal carcinogenicity studies and additional description of foam appearance.

Budenofalk (budesonide) 9mg gastro-resistant granules

The licensed indication has been updated from collagenous colitis to microscopic colitis, and information relating to this added throughout the SPC.

Clarelux (clobetasol propionate) 500 microgram/g cutaneous foam in pressurised container

SPC has been updated with warning that prolonged use may result in serious undesirable effects;if treatment with local corticosteroid (CS) is clinically justified beyond 2weeks, a less potent CS should be considered. Repeated but short courses may be used to control exacerbations.

Cellcept (mycophenolate mofetil) products

SPCs now warn that as mycophenolic acid has a cytostatic effect on B- and T-lymphocytes, an increased severity of COVID-19 may occur, thus dose reduction or discontinuation should be considered for patients in cases of clinically significant COVID-19.

Desizon (zonisamide) oral suspension

SPC now states hyperammonaemia has been reported with or without encephalopathy with zonisamide. If unexplained lethargy or changes in mental status occur during treatment, hyperammonaemic encephalopathy should be considered and ammonia levels measured.

Dermovate (clobetasol) preparations

SPC updated with a boxed warning and with warnings on osteonecrosis, serious infections and immunosuppression, as part of PRAC recommendation regarding the risks of the long-term use of this potent topical corticosteroid.

Diflucan (fluconazole) products

SPC updated to note exposure to tolvaptan (CYP3A4 substrate) is significantly increased when co-administered with fluconazole (moderate CYP3A4 inhibitor), with risk of significant increase in adverse reactions; tolvaptan dose should be used when they are used concomitantly.

Elvanse (lisdexamfetamine dimesylate) Capsules- all presentations

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

Feldene (piroxicam) 0.5% w/w Gel

The SPC has been updated to include drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) as one of the severe cutaneous reactions reported with use of systemic of piroxicam (possibility of this occurring with topical administration cannot be ruled out).

Feldene (piroxicam) – all products

The SPCs have been updated to include reference to ‘Fixed Drug Eruption’ as an adverse event of unknown frequency.

Klaricid (clarithromycin) preparations

SPC now notes potential interaction with methadone, a CYP3A4 substrate, whose concentration may be elevated, when given concomitantly with clarithromycin. Close monitoring is advised.

Locoid (hydrocortisone butyrate) products

SPC notes now licensed in infants above 3 months of age and contraindicated in yeast or parasitic infections. Warnings regarding glaucoma; instruction to wash hands; information regarding long term use, use under occlusion and use in large areas are all enhanced.

Lustral (sertraline) film coated tablets

The SPC has been updated in line with the PRAC recommendation regarding postpartum haemorrhage. Observational data indicate an increased risk (less than 2-fold) of postpartum haemorrhage following SSRI/SNRI exposure within the month prior to birth.

Molipaxin (trazodone hydrochloride) tablets – all strengths

Information added regarding the risk of serotonin syndrome when co-administered with buprenorphine/opioids.

Nimenrix (meningococcal groups A, C, W-135 and Y conjugate vaccine) powder and solvent for solution for injection in pre-filled syringe

Lymphadenopathy has been added to SPC as an adverse effect of unknown frequency.

Nytol (diphenhydramine) tablets

Hypoesthesia and restless leg syndrome have been added as potential adverse effects of treatment.

Paludrine/Avloclor Anti-Malarial Travel Pack Chloroquine & Proguanil Anti-Malarial Tablets

SPC now warns cases of suicidal behaviour/psychiatric disorders (PDs) have been reported in patients on chloroquine, including those with no prior history of PDs. Patients should be advised to seek medical advice

promptly if they experience psychiatric symptoms during treatment.

Reminyl (galantamine) preparations

QTc prolongation has been reported in patients using therapeutic doses and torsade de pointes in association with overdoses. Use cautioned in patients with prolonged QTc interval (QTcI), taking drugs affecting QTcI, or with pre-existing cardiac disease or electrolyte disturbances.

Sabril (vigabatrin) – all presentations

SPC notes that cases of intramyelinic oedema (IME), reversible following drug discontinuation, have been reported, particularly in infants treated for infantile spasms (frequency unknown).

Solu-Medrone (methylprednisolone sodium succinate) 40 mg Powder for Injection

This healthcare professional letter advises of a lactose-free formulation change, plans to initiate transition to the lactose-free formulation and risk of serious allergic reactions if formulations are confused.

Targinact (oxycodone/naloxone) prolonged-release tablets

SPC now advises that caution is required when using Targinact for restless legs syndrome in patients with additional sleep apnoea syndrome due to the additive risk of respiratory depression.

Testogel (testosterone) gel

SPC updated in line with PRAC recommendation to highlight caution in use in those with risk factors for venous thromboembolism owing to reports of thrombotic events with treatment.

Vermox (mebendazole) tablets

SPC updated to recommend that owing to limited data, treatment should not be given to those <1 year, and that in those aged 1-2 years mebendazole should only be given if the potential benefit justifies the potential risk.

Venladex (venlafaxine) XL 75 mg and 225mg prolonged-release tablets

Further information added to SPC in relation to discontinuing treatment, including severe effects such as suicide/suicidal thoughts and aggression. SPC also now notes that SSRIs/SNRIs may increase the risk of postpartum haemorrhage.

Zimovane (zopiclone) film-coated tablets

Due to reduced elimination, SPC advises a lower dose of 3.75 mg in hepatic dysfunction and contraindicates use in severe hepatic insufficiency due to risk of encephalopathy. Caution also advised in patients with depression with treatment for no longer than 4 weeks.

Zonegran (zonisamide) Hard Capsules-all strengths

SPC information has been expanded to warn that metabolic acidosis has the potential to lead to hyperammonaemia, which has been reported with or without encephalopathy during zonisamide treatment.