Medicines Safety Assurance Tool

September 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

NHS
Midlands and Lancashire
Commissioning Support Unit

Update From The Cas Helpdesk: Changes To Mhra Alerts And Amendments To The Website

17 September 2020

The Medicines and Healthcare products Regulatory Agency (MHRA) is now an accredited issuer of National Patient Safety Alerts. This means there will be some changes to what you receive from CAS as set out in the attached document. There are also some changes to the website and a reminder to organisations to register out of hours email addresses with us if you have them.

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Opioids: risk of dependence and addiction

23 September 2020

New recommendations following a review of the risks of dependence and addiction associated with prolonged use of opioid medicines (opioids) for non-cancer pain. Before prescribing opioids, discuss with the patient the risks and features of tolerance, dependence, and addiction, and agree together a treatment strategy and plan for end of treatment.

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Transdermal fentanyl patches for non-cancer pain: do not use in opioid-naive patients

23 September 2020

Following a review of the risks associated with use of opioid medicines for non-cancer pain, the Commission on Human Medicines (CHM) has recommended that fentanyl transdermal patches are contraindicated in opioid-naive patients in the UK.

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Methotrexate once-weekly for autoimmune diseases: new measures to reduce risk of fatal overdose due to inadvertent daily instead of weekly dosing

23 September 2020

In autoimmune conditions and some cancer therapies, methotrexate should be taken once a week; however, we continue to receive reports of inadvertent overdose due to more frequent dosing (including daily administration). New measures have been implemented to prompt healthcare professionals to record the day of the week for intake and to remind patients of the dosing schedule and the risks of overdose.

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Insulins (all types): risk of cutaneous amyloidosis at injection site

23 September 2020

Cutaneous amyloidosis at the injection site has been reported in patients using insulin and this may affect glycaemic control. Remind patients to rotate injection sites within the same body region.

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Safety leaflet on opioid medicines and the risk of addiction

This safety leaflet aims is to help support patients and their family in using opioid medicines safely and reduce the risks of harm.

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Summary of Product Characteristics updates

September 2020

Atrovent (ipratropium) respirator solutions
SPC now notes that only specialists in respiratory medicine should initiate and clinically manage use of nebulisers and associated nebulised medicines at home for acute treatment of asthma in children and adolescents.

Bupeaze (buprenorphine) Transdermal Patches – all strengths
SPCs revised to warn concomitant administration of buprenorphine and other serotonergic agents (such as selective serotonin re-uptake inhibitors or tricyclic antidepressants) may result in serotonin syndrome.

Co-Diovan 80/12.5 mg (valsartan/ hydrochlorothiazide) tablets
Information on choroidal effusion has been added to the warning regarding acute myopia and secondary angle-closure glaucoma (PRAC has recommended the addition of this to all SPCs of thiazide and thiazide-like diuretics).

Crestor (rosuvastatin) tablets
Concomitant use with sofosbuvir/velpatasvir/voxilaprevir is now contraindicated. Also caution advised for concomitant use with medicines which increase the AUC of rosuvastatin by less than 2 fold, though no starting dose reduction is required.

Dexamfetamine sulfate tablets
SPC now states that children of mothers who are dependent on amfetamine are at an increased risk of premature birth and reduced birth weight and also may also develop withdrawal symptoms like dysphoria, including hyperexcitability and pronounced exhaustion.

Dianette (Cyproterone acetate/ Ethinylestradiol)
The SPC has been updated in line with the outcome of the Article-31 referral, relating to the risk of meningioma with cyproterone. Although available data do not indicate a risk for low-dose medicines, they should not be used in people who have or have had a meningioma

Proposed action

☐ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

dose medicines, they should not be used in people who have or have had a meningioma.

Efexor (venlafaxine) XL150 mg hard prolonged release capsules
SPC notes suicide/suicidal thoughts and aggression have been reported during changes in dose and, during discontinuation therefore patients should be closely monitored. Risk of withdrawal symptoms may be dependent on duration and dose of therapy and rate of dose reduction.

Efexor XL 75 and 225 mg prolonged-release capsules, hard products
SPCs have been updated with information regarding discontinuation of treatment with venlafaxine.

Epanutin (phenytoin) Infatabs 50 mg chewable tablets and 30mg/5ml oral Suspension
SPCs revised to warn that angioedema has been reported in patients treated with phenytoin and fosphenytoin and treatment should be discontinued immediately if symptoms of angioedema, such as facial, perioral, or upper airway swelling occur.

Humalog (insulin lispro) products
SPCs now advise patients must continuous rotate injection site to reduce risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions.

Inegy Tablets (ezetimibe/simvastatin) - all strengths
Dosage recommendation for ticagrelor has been added to table on drug interactions associated with increased risk of myopathy/rhabdomyolysis, as has a statement on co-administration of ticagrelor with simvastatin causing increase in simvastatin Cmax and AUC.

Laxido (macrogol) Paediatric Plain powder for oral solution
Data on sodium content is now included. It contains 93 mg of sodium per sachet, equivalent to approximately 4.6% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Lisoretic (hydrochlorothiazide/lisinopril dihydrate) tablets
SPC now highlights risk of choroidal effusion with visual field defect, transient myopia and acute angle-closure glaucoma. Treatment of these adverse requires rapid discontinuation of treatment, with medical/surgical management of intraocular pressure remains uncontrolled

treatment, with medical/surgical management of intraocular pressure remains uncontrolled.

Livial (tibolone) tablets
SPC now includes updated warnings regarding increased risk of breast cancer after HRT cessation, which corresponds to duration of treatment. It highlights the increased risk in users of oestrogen-only and tibolone is lower than seen in users of oestrogen-progestogen combinations.

Loperamide tablets
SPC now highlights that caution is needed in patients with a history of drug abuse as loperamide is an opioid and addiction is observed with opioids as a class.

Lyumjev (insulin lispro) formulations
SPC updated to note that cutaneous amyloidosis, as well as lipodystrophy, may occur at the injection site and delay local insulin absorption. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing these reactions.

Maxidex (dexamethasone)
SPC updated following MHRA recommendation to add warnings that because of the possibility of reduced glucose tolerance/diabetes mellitus with topical ophthalmic corticosteroids, caution is recommended when administering to patients with a personal or family history of diabetes.

Oramorph (morphine) Oral Solution
SPC states decreased exposure to oral P2Y12 inhibitor in acute coronary syndrome may occur with concomitant use, likely due to reduced GI motility. If concomitant use cannot be avoided, and fast P2Y12 inhibition crucial, use of a parenteral P2Y12 inhibitor may be considered.

OxyNorm (oxycodone) 10 and 50 mg/ml solution for injection or infusion
Information on conversion from morphine and statements on consideration of patient's previous history of analgesic requirements & use of lowest effective dose have been added to SPC, as have data on carcinogenicity (no increase tumour incidence in rats at doses up to 6mg/kg/d).

Progynova (estradiol valerate) 1 and 2 mg tablets
SPCs have been updated as a result of the PRAC signal on hormone replacement therapy and new information on the known risk of breast cancer.

Seroxat (paroxetine) tablets
Microscopic colitis has been added as a potential adverse effect of treatment (frequency not known.

Suboxone (buprenorphine/naloxone) sublingual film- all strengths
SPCs now warn that concomitant administration of Suboxone and other serotonergic agents, such as MAO inhibitors, SRIs, SNRIs or tricyclic antidepressants may result in serotonin syndrome, a potentially life-threatening condition.

Tamiflu (oseltamivir) 6 mg/ml Powder for Oral Suspension
SPC now warns that excipient sorbitol may cause gastrointestinal discomfort and can have a mild laxative effect, and sodium benzoate (E211) may increase jaundice in newborn babies (up to 4 weeks old).

Trelegy Ellipta 92 micrograms/55 micrograms/22 micrograms (fluticasone furoate/umeclidinium bromide/vilanterol trifenatate) inhalation powder, pre-dispensed
SPC updated with adverse reactions of hypersensitivity reactions, including anaphylaxis, angioedema, urticaria, and rash.

Ventolin (salbutamol) Nebules 2.5 and 5.0 mg
SPCs updated to advise private purchase of nebuliser devices for use at home to deliver rescue therapy for acute treatment of asthma in children & adolescents is not recommended; only respiratory specialists should initiate and clinically manage their use in this setting.

Zydol (tramadol) products
SPC now notes regular use during pregnancy may cause drug dependency in the foetus and withdrawal symptoms in the neonate; administration to nursing women is not recommended as it may be secreted in breast milk and cause respiratory depression in the infant.