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Medicines Safety Assurance Tool November 2017



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

Unbranded Led Decorative Lighting Chains, Model CI100: Risk Of Electric Shock Due To Inadequate Construction - Remove From Use

Central Alerting System | 22 Nov 2017

There is a risk of electric shock due to inadequate construction of unbranded decorative LED lighting chains. Implicated units should be removed immediately from use in health and social care premises. This risk was highlighted via the EU Rapid Reaction System and the Electrical Safety First organisation have issued a recall in relation to the products. As there is the potential for festive lights of this type to be utilised in communal areas, in certain settings, this Alert is being issued as a precautionary measure.

https://www.cas.dh.gov.uk/ViewAndAcknowledgment/viewAttachment.aspx?Attachment_id=102871

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Quinine: reminder of dose-dependent QT-prolonging effects; updated medicine interactions

Medicines and Healthcare products regulatory agency | 24 Nov 2017

Quinine has dose-dependent QT-interval-prolonging effects and should be used with caution in patients with risk factors for QT prolongation or in those with atrioventricular block.

<https://www.gov.uk/drug-safety-update/quinine-reminder-of-dose-dependent-qt-prolonging-effects-updated-medicine-interactions>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Oral tacrolimus products: reminder to prescribe and dispense by brand name only

Medicines and Healthcare products regulatory agency | 24 Nov 2017

Inadvertent switching between tacrolimus products has been associated with reports of toxicity and graft rejection.

<https://www.gov.uk/drug-safety-update/oral-tacrolimus-products-reminder-to-prescribe-and-dispense-by-brand-name-only>

Proposed action

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



Action taken

Status

Unassigned

Action due date

Date completed

Antiepileptic drugs: updated advice on switching between different manufacturers' products

Medicines and Healthcare products regulatory agency | 24 Nov 2017

In addition to the 3 risk-based categories of antiepileptic drugs, patient-related factors should be considered when deciding whether it is necessary to maintain continuity of supply for a specific product.

<https://www.gov.uk/drug-safety-update/antiepileptic-drugs-updated-advice-on-switching-between-different-manufacturers-products>

Proposed action

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



Action taken

Status

Unassigned

Action due date

Date completed

Updates to Public Health England's Green Book chapter on live attenuated vaccines

Medicines and Healthcare products regulatory agency | 24 Nov 2017

Further to our previous advice in 2016, Public Health England have updated their guidance about live vaccination of infants born to a mother who received immunosuppressive biological therapy during pregnancy.

<https://www.gov.uk/drug-safety-update/updates-to-public-health-england-s-green-book-chapter-on-live-attenuated-vaccines>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Calcichew-D3 500mg/400 IU Caplets

Medicines and Healthcare products Regulatory Agency | 28 Nov 2017

Takeda UK Ltd are issuing a company-led drug alert for one batch of Calcichew-D3 500mg/400 IU Caplets due to traces of a non-approved excipient

<https://www.gov.uk/drug-device-alerts/calcichew-d3-500mg-400-iu-caplets>

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 Update

electronic Medicines Compendium | Nov 2017

Aptivus (tipranavir) capsules and oral solution

Co-administration of tipranavir and low dose ritonavir, with antipsychotics such as lurasidone is contraindicated due to potential serious and/or life threatening events, including coma.

<http://www.medicines.org.uk/emc/medicine/22331>

Becanase (beclometasone) Aqueous Nasal Spray

Visual disturbance has been reported with systemic and topical corticosteroid use (frequency not known). In the event of visual disturbance, the SPC advises to consider referral to an ophthalmologist for evaluation of possible causes.

<http://www.medicines.org.uk/emc/medicine/81>

Bydureon (exenatide) 2 mg powder and solvent for prolonged-release suspension for injection in pre-filled pen

Bydureon is now also licensed for use in combination with basal insulin, when the therapy in use, together with diet and exercise, does not provide adequate glycaemic control. The entire SPC has been updated to include information about combination use with insulin.

<http://www.medicines.org.uk/emc/medicine/29798>

Calmurid Cream (Urea and lactic acid)

New information includes: not to be used extensively in patients with severe renal impairment; avoid contact with eyes/surrounding area; do not apply on inflamed skin or open wounds; urea may enhance skin penetration of other substances (e.g. corticosteroids, dithranol, 5-FU).

<http://www.medicines.org.uk/emc/medicine/689>

Differin Gel (adapalene)

A warning that exposure to sunlight and UV light irradiation should be minimised during use has been added; existing warnings have also been updated.

<http://www.medicines.org.uk/emc/medicine/692>

Elvanse (lisdexamfetamine)

Chest pain (frequency = uncommon in children and adolescents, and common in adults) has been added as a potential adverse effect from treatment.

<http://www.medicines.org.uk/emc/medicine/30377>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Emend (aprepitant) 125 mg powder for oral suspension

Statement has been added to SPC advising that suspension should be prepared and the dose measured by healthcare professional only. Also the dosing nomogram has been replaced with weight based dosing instructions in mg/kg.

<http://www.medicines.org.uk/emc/medicine/32355>

Exviera (dasabuvir) tablets

The SPC has been updated to incorporate a warning about depression or psychiatric illness.

<http://www.medicines.org.uk/emc/medicine/29785>

Jylamvo (Methotrexate) 2 mg/ml oral solution -Guide for Healthcare Professionals

The guide has been produced to help mitigate the potential risk of medication errors in patients being treated for arthritis and psoriasis in a weekly regimen. It also describes the risks, and what to do in the event of a medication error.

<https://www.medicines.org.uk/emc/RMM.1064.pdf>

Klaricid (clarithromycin) – all formulations

The SPC now advises that patients taking oral contraceptives should be warned that if diarrhoea, vomiting or breakthrough bleeding occur there is a possibility of contraceptive failure.

<http://www.medicines.org.uk/emc/medicine/16945>

Malarone (atovaquone and proguanil) Paediatric Tablets

Indication has been corrected to the treatment of acute, uncomplicated *P. falciparum* malaria in children weighing ≥ 5 kg and < 11 kg (previously stated < 10 kg) and posology has been updated to reflect this range.

<http://www.medicines.org.uk/emc/medicine/9745>

Motilium (domperidone) 10mg Film-coated Tablets

The SPC now notes that concomitant use with apomorphine is contra-indicated unless the benefit of the co-administration outweighs the risks, and only if the recommended precautions for co-administration mentioned in the apomorphine SPC are strictly fulfilled.

<http://www.medicines.org.uk/emc/medicine/26666>

Mysimba (8 mg naltrexone /90 mg bupropion) prolonged-release tablets

SPC now includes details of CV outcomes trial of patients at increased risk of CV event, which found mean increases from baseline in systolic and diastolic BP of ~1 mmHg vs. placebo. It notes in clinical practice, as with other bupropion products, hypertension has been reported.

<http://www.medicines.org.uk/emc/medicine/33484>

Norgeston (levonorgestrel 30 micrograms)

SPC has been updated with data on the interactions with HIV/HCV protease inhibitors, non-nucleoside reverse transinhibitors, and CYP3A4-inducers and inhibitors.

<http://www.medicines.org.uk/emc/medicine/1834>

Pradaxa (dabigatran) hard capsules (all strengths)

Sections 4.2 (Posology and method of administration), 4.4 (Special warnings and precautions for use) and 5.1 (Pharmacodynamic properties) have been updated to include information regarding catheter ablation for atrial fibrillation.

<http://www.medicines.org.uk/emc/medicine/24839>

Prednisolone 25 tablets

SPC now highlights that caution is required in patients with systemic sclerosis due to an increased incidence of (possibly fatal) scleroderma renal crisis with hypertension and decreased urinary output observed with a daily dose of 15 mg or more of

<http://www.medicines.org.uk/emc/medicine/26755> prednisolone.

Priorix (live Measles, Mumps and Rubella vaccine)

The method of administration has been updated to include in the deltoid region or in the anterolateral area of the thigh; information about the monovalent or combination vaccines that it can be given with has also been updated.

<http://www.medicines.org.uk/emc/medicine/2054>

Promixin (colistimethate sodium) Powder for Nebuliser Solution

The previous dosing table has been replaced by two tables that show data on low ("1 MIU)" and high "(2 MIU) doses, both with different nebulisers.

<http://www.medicines.org.uk/emc/medicine/13495>

Requip (ropinirole) Tablets

Dopamine agonist withdrawal syndrome (DAWS) has been added as an adverse effect (unknown frequency). Section 4.4 has been updated with information on DAWS and hallucinations. New sub section on fertility has been added.

<http://www.medicines.org.uk/emc/medicine/2056>

Tambocor (flecainide) – all presentations

Section 4.8 (undesirable effects) now includes arthralgia and myalgia.

<http://www.medicines.org.uk/emc/medicine/19589>

Tarivid (ofloxacin) 400 mg Tablets

Due to increase in resistance to N. gonorrhoeae, it should not be used as empirical treatment in suspected gonococcal infection, unless the pathogen has been identified and confirmed as susceptible to ofloxacin. Various changes have been made to indications and dosing sections.

<http://www.medicines.org.uk/emc/medicine/25496>

Tarivid (ofloxacin) 200 mg Tablets

Section 4.1 now includes more specific indications, and section 4.4 advises due to increase in resistance to N. gonorrhoeae, ofloxacin should not be used as empiric treatment in suspected gonococcal infection unless the pathogen is confirmed as susceptible to ofloxacin.

<http://www.medicines.org.uk/emc/medicine/25497>

Toujeo 300 units/ml solution for injection in a pre-filled pen

SPC now notes: Toujeo must not be drawn from the cartridge of the pre-filled pen into a syringe, to avoid dosing errors; a new sterile needle must be attached before each injection (do not re-use); insulin labels must be checked prior to each injection to avoid medication errors.

<http://www.medicines.org.uk/emc/medicine/30586>

Tresiba (insulin degludec) 100 units/mL, 200 units/mL Pre filled (FlexTouch), 100 units/mL Cartridge (Penfill)

Tresiba must not be drawn from the cartridge of the pre-filled pen into a syringe, to avoid dosing errors and potential overdose. Patients should always use a new insulin pen needle, as re-use increases risk of blocked needles, which may cause under- or overdosing.

<http://www.medicines.org.uk/emc/medicine/27360>

Valcyte (valganciclovir) 450 mg Film-Coated Tablets

Women of child bearing potential must use effective contraception during and for at least 30 days after treatment [previously advised during treatment only]. Use in patients with known hypersensitivity to aciclovir is now cautioned [previously contraindicated].

<http://www.medicines.org.uk/emc/medicine/9315>

Viekirax (ombitasvir, paritaprevir, ritonavir) tablets

The SPC has been updated to incorporate a warning about depression or psychiatric illness.

<http://www.medicines.org.uk/emc/medicine/29784>

Xarelto (rivaroxaban) film-coated tablets

As with other anticoagulants, the possibility may exist that patients are at increased risk of bleeding in case of concomitant use with SSRIs or SNRIs. When concomitantly used in the clinical program, numerically higher rates of clinically relevant bleeding were observed.

SPC now states when 'extended prevention of recurrent DVT and PE' is indicated (after ≥ 6 months therapy for DVT/PE), recommended dose is 10mg daily; 20mg should be considered in those at high risk of recurrent DVT/PE. Duration/dose should be based on benefit vs. bleeding risk.

<http://www.medicines.org.uk/emc/medicine/29371>

Xultophy 100 units/ml insulin degludec + 3.6 mg/mL liraglutide solution for injection in a pre-filled pen

The SPC has been updated with advice to patients and healthcare professionals on how to avoid dosing errors and potential overdose.

<http://www.medicines.org.uk/emc/medicine/29493>

Xyrem (sodium oxybate) oral solution

Changes have been made to the breast-feeding statements and two new adverse effects, seborrhoea and increased libido, both of unknown frequency, have been added to the SPC.

<http://www.medicines.org.uk/emc/medicine/17364>

Zytiga (abiraterone) 500 mg film-coated tablets

SPC has been updated with new indication of treatment (with prednisone or prednisolone) of newly diagnosed high risk metastatic hormone sensitive prostate cancer in adult men in combination with androgen deprivation therapy.

<http://www.medicines.org.uk/emc/medicine/32865>