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Medicines Safety Assurance Tool November 2018

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Midlands and Lancashire
Commissioning Support Unit

Hydrochlorothiazide: risk of non-melanoma skin cancer, particularly in long-term use

Medicines and Healthcare Products Regulatory Agency | 14 November 2018

This update advises that patients taking hydrochlorothiazide-containing products should be informed of the cumulative, dose-dependent risk of non-melanoma skin cancer, particularly in long-term use, and the need to regularly check for (and report) any suspicious skin lesions or moles. Counsel patients to limit exposure to sunlight and UV rays and to use adequate sun protection.

<https://www.gov.uk/drug-safety-update/hydrochlorothiazide-risk-of-non-melanoma-skin-cancer-particularly-in-long-term-use>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Systemic and inhaled fluoroquinolones: small increased risk of aortic aneurysm and dissection; advice for prescribing in high-risk patients

Medicines and Healthcare Products Regulatory Agency | 14 November 2018

Owing to these reports, this advice details that in patients at risk for aortic aneurysm and dissection (e.g. family history), fluoroquinolones should only be used after careful assessment of the benefits and risks and after consideration of other therapeutic options.

<https://www.gov.uk/drug-safety-update/systemic-and-inhaled-fluoroquinolones-small-increased-risk-of-aortic-aneurysm-and-dissection-advice-for-prescribing-in-high-risk-patients>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

European CHMP endorses suspension or restrictions of quinolone and fluoroquinolone antibiotics due to disabling and potentially permanent adverse effects

European Medicines Agency | 16 November 2018

Following a PRAC review of adverse effects involving muscles, tendons and bones and the nervous system, the CHMP has endorsed suspension of medicines containing cinoxacin, flumequine, nalidixic acid, and pipemidic acid and restrictions on use of other fluoroquinolone antibiotics.

https://www.ema.europa.eu/documents/referral/quinolone-fluoroquinolone-article-31-referral-disabling-potentially-permanent-side-effects-lead_en.pdf

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Cannabidiol oil – potential adverse effects and drug interactions

Specialist Pharmacy Services | 30 November 2018

Due to an increasing popularity of self-administration of over-the-counter bought cannabidiol oil, doctors and pharmacists should be aware of its potential adverse effects and interactions. Available data suggests it interacts with cytochrome p450 enzymes.

<https://www.sps.nhs.uk/articles/cannabidiol-oil-potential-adverse-effects-and-drug-interactions/>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Nutilis Clear Product Update – New Scoop and Mixing Instructions

Pharmaceutical Services Negotiating Committee | 30 November 2018

Thickened drinks are changing from 'Stage 1, 2 and 3' to IDDSI (International Dysphagia Diet Standardisation Initiative) Levels 1 – 4. To meet these changes, the scoops in tins of Nutilis Clear are changing from a purple 3g scoop to a green 1.25g scoop with new directions for use

<https://psnc.org.uk/our-news/nutilis-clear-product-update-new-scoop-and-mixing-instructions/>

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 | November 2018

Actiq (fentanyl) Lozenges (all strengths)

SPCs now warns that in absence of adequate pain control, the possibility of hyperalgesia, tolerance and progression of underlying disease should be considered. A fentanyl dose reduction or discontinuation of treatment or treatment review may be indicated.

<https://www.medicines.org.uk/emc/product/6919/smpc>

Differin (adapalene) Gel

The SPC has been updated to reflect that due to the limited available data and because a very weak cutaneous passage of adapalene is possible, use of this product is contraindicated in pregnancy, or in women planning a pregnancy.

<https://www.medicines.org.uk/emc/product/921/smpc>

Aprovel and CoAprovel tablets

Anaphylaxis has been added as a potential adverse effect from treatment (frequency unknown) to the SPC.

<https://www.medicines.org.uk/emc/product/3049/smpc>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Entocort (budesonide) CR 3mg Capsules

SPC has been updated with new indication of the maintenance of remission in patients with microscopic colitis and dose is 6 mg once daily in the morning, or the lowest effective dose.

<https://www.medicines.org.uk/emc/product/872/smpc>

Epiduo (adapalene and benzoyl peroxide) Gel

Application site burn has been added as a potential adverse effect of treatment (frequency unknown) to the SPC.

<https://www.medicines.org.uk/emc/product/451/smpc>

Forxiga (dapagliflozin) 5 mg film coated tablets

SPC has updated information with respect to use in renal impairment. It should not be initiated where the glomerular filtration rate (GFR) is < 60 mL/min, and discontinued where GFR is persistently below 45mL/min. No dosage adjustment is required in renal impairment.

<https://www.medicines.org.uk/emc/product/2865/smpc>

Gyno-Daktarin (miconazole) 20mg/g cream

The SPC now advises to administer the contents of one applicator once daily before bedtime deeply into vagina for 7 days in adults. For vulvitis the cream should be applied topically twice daily.

<https://www.medicines.org.uk/emc/product/1437/smpc>

Hydrea (hydroxycarbamide) Capsules

Systemic and cutaneous lupus erythematosus has been added as a potential adverse effect of treatment (very rare) to the SPC.

<https://www.medicines.org.uk/emc/product/271/smpc>

Influvac sub-unit Tetra and Tetra MYL 5- valent influenza vaccines

The SPC has been updated with paediatric dosing. Children 3 - 17 years should be administered a 0.5 ml dose. Children <9 years, who have not previously been vaccinated with a seasonal influenza vaccine should be given a second dose of 0.5 ml after an interval of at least 4 weeks.

<https://www.medicines.org.uk/emc/product/9381/smpc>

Lamictal (lamotrigine) tablets

The SPC now reports that arrhythmogenic ST-T abnormality and typical Brugada ECG pattern as well as haemophagocytic lymphohistiocytosis have been reported in patients treated with lamotrigine.

<https://www.medicines.org.uk/emc/product/8052/smpc>

Levitra (vardenafil) film-coated tablets (all strengths/presentations)

Section on effects on vision of the SPC has been updated to reflect data from two post-marketing authorisation observational studies, which indicate an increased risk of acute non-arteritic ischemic optic neuropathy in men with erectile dysfunction following exposure to PDE5 inhibitors.

<https://www.medicines.org.uk/emc/product/7629/smpc>

Lyflex (baclofen) 5mg/5ml Oral Solution

SPC now warns that cases of central sleep apnoea syndrome have been observed with baclofen at high doses (≥ 100 mg) in patients who are alcohol dependent.

<https://www.medicines.org.uk/emc/product/5563/smpc>

Metoject (methotrexate) PEN solution for injection in pre-filled pen

SPC updated to note that pulmonary alveolar haemorrhage and osteonecrosis of the jaw have been reported, and that concomitant use with nitrous oxide should be avoided (potentiates effect of methotrexate on folate, yielding increased toxicity).

<https://www.medicines.org.uk/emc/product/5443/smpc>

Mucogel (aluminium and magnesium Hydroxide) suspension

Hypermagnesemia and abdominal pain have been added to SPC as adverse effects. SPC now warns that in young children, the use of magnesium hydroxide can produce a hypermagnesemia, especially if they present with renal impairment or dehydration.

<https://www.medicines.org.uk/emc/product/6444>

Plavix (clopidogrel) 75 and 300mg tablets

Insulin autoimmune syndrome has been added to SPCs as an adverse effect (unknown frequency). This can lead to severe hypoglycaemia, particularly in patients with HLA DRA4 subtype (more frequent in the Japanese population).

<https://www.medicines.org.uk/emc/product/5935/smpc>

Sabril (vigabatrin) – all formulations

The SPC warns that concomitant use of vigabatrin and clonazepam may exacerbate sedation therefore need for concomitant use must be carefully assessed.

<https://www.medicines.org.uk/emc/product/4279/smpc>

Seroxat (paroxetine) preparations

Bruxism (teeth clenching) has been added as a potential adverse effect of treatment (frequency unknown) to the SPC.

<https://www.medicines.org.uk/emc/product/7594/smpc>

Sofradex (framycetin, dexamethasone and gramicidin) Ear / Eye Drops

The SPC has been updated to note that prolonged use may lead to the risk of adrenal suppression in infants.

<https://www.medicines.org.uk/emc/product/2253/smpc>

Tildiem (diltiazem hydrochloride) Prolonged-Release Tablets (all strengths)

SPCs updated to advise that diltiazem may induce bronchospasm, especially in patients with pre-existing bronchial hyper-reactivity. An increased risk of depression has also been reported when diltiazem is co-administered with beta-blockers.

<https://www.medicines.org.uk/emc/product/4970/smpc>

Timoptol (timolol) 0.25% and 0.5% w/v Eye Drops Solution

SPC now warns benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect tear film and corneal surface. It should be used with caution in dry eye patients and in patients where cornea may be compromised.

Prolonged use should be monitored.

<https://www.medicines.org.uk/emc/product/5110/smpc>

Varivax (live varicella vaccine)

Aseptic meningitis has been added as an adverse effect to the SPC. Complications associated with varicella from the vaccine strain (including herpes zoster and disseminated disease) have been reported in immunocompromised or immunocompetent individuals during post-marketing surveillance.

<https://www.medicines.org.uk/emc/product/5582/smpc>

Xadago (safinamide methanesulfonate) tablets (all strengths)

SPCs updated to recommend monitoring of patients when safinamide is taken with drugs that are breast cancer resistance protein substrates (e.g. rosuvastatin) and to refer to their SPCs to determine if a dose adjustment is needed.

<https://www.medicines.org.uk/emc/product/2159/smpc>

Yentreve (duloxetine) 40mg hard gastro-resistant capsules

Interstitial lung disease and eosinophilic pneumonia have been added as rare adverse events. The SPC also now notes some patients may benefit from starting treatment at 20mg twice daily before increasing to 40mg twice daily, this may decrease the risk of nausea and dizziness.

<https://www.medicines.org.uk/emc/product/7441/smpc>

Zimovane (zopiclone) LS 3.75mg film-coated tablets

The SPC has been updated with fertility data from >1000 pregnancies which have not demonstrated evidence of malformations during first trimester. However, an increased incidence of cleft lip and palate has been reported in addition to cases of severe neonatal respiratory depression in late pregnancy.

<https://www.medicines.org.uk/emc/product/2854/smpc>