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Medicines Safety Assurance Tool May-19

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Midlands and Lancashire
Commissioning Support Unit

Influenza Season 2018/19: Use of Antiviral Medicines in Primary Care

Central Alerting System | 08 May 2019

The most recent surveillance data from Public Health England (PHE) indicates that circulation of influenza in the community has returned to baseline levels. GPs and other prescribers working in primary care should no longer prescribe antiviral medicines, for the prophylaxis and treatment of influenza on an FP10 prescription form. Community pharmacists should no longer supply antiviral medicines in primary care, on presentation of an FP10 prescription form.

<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102861>

Proposed action

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



Action taken

Status

Unassigned



Action due date

Date completed

Yellow Card: please help to reverse the decline in reporting of suspected adverse drug reactions

Medicines and Healthcare products Regulatory Agency | 20 May

The MHRA has noted a decline in reporting of suspected adverse drug reactions (ADRs) to the Yellow Card Scheme from key reporter groups, including GPs, pharmacists, and hospital doctors in 2018. It urges Yellow Card reporting to help understand the benefits and risks of medicines.

<https://www.gov.uk/drug-safety-update/yellow-card-please-help-to-reverse-the-decline-in-reporting-of-suspected-adverse-drug-reactions>

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 | May 2019

Accrete D3 One a Day 1000 mg / 880 IU (calcium carbonate with colecalciferol) Chewable Tablets

The SPC has been updated to advised that this medicinal product contains 152.89 mg sorbitol (E420) in each tablet.

<https://www.medicines.org.uk/emc/product/8506/smpc>

AROVI (enoxaparin sodium) pre-filled syringe with safety device (all strengths)

The SPC has been updated to reflect the removal of the option of IV administration.

<https://www.medicines.org.uk/emc/product/9332/smpc>

Bascellex (imiquimod) cream

The SPC now warns that patients should be instructed not to smoke or go near naked flames due to risk of severe burns.

<https://www.medicines.org.uk/emc/product/9347/smpc>

Cetraxal Plus 3mg/ml + 0.25mg/ml (fluocinolone acetonide, ciprofloxacin hydrochloride) ear drops solution

Sections 4.4 and 4.8 of the SPC have been updated to advise visual disturbance may be reported with systemic and topical corticosteroid use. If symptoms such as blurred vision or other visual disturbances occur, the patient should be considered for referral to an ophthalmologist.

<https://www.medicines.org.uk/emc/product/9805/smpc>

Detrunorm (propiverine hydrochloride) XL Modified-Release Capsules (all strengths)

The SPC warns that for patients receiving concomitant treatment with drugs that are potent inhibitors of CYP 3A4 combined with methimazole; treatment should start at 15 mg per day.

<https://www.medicines.org.uk/emc/product/3549/smpc>

Proposed action

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

Action taken

Status

Unassigned

Action due date

Date completed



Jext (adrenaline) 150 and 300 micrograms Solution for Injection in pre-filled pen

The SPC has been revised to state that in patients with thick sub-cutaneous fat layer, there is a risk of adrenaline being administered in sub-cutaneous tissue which may result in a slower adrenaline absorption and a suboptimal effect. This may increase the need for a second Jext injection

<https://www.medicines.org.uk/emc/product/5748/smpc>

Ketovite Tablets

SPC has been revised to warn that biotin may interfere with laboratory tests that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results, depending on assay. Risk is higher in children/patients with renal impairment.

<https://www.medicines.org.uk/emc/product/1052/smpc>

Lipitor (atorvastatin) tablets

Lupus-like syndrome has been added as a very rare potential adverse effect of treatment to the SPC.

<https://www.medicines.org.uk/emc/product/5237/smpc>

Neurontin (gabapentin) 600mg Film-coated Tablets

Dysphagia has been added as an uncommon potential adverse effect of treatment to the SPC.

<https://www.medicines.org.uk/emc/product/3197/smpc>

Pradaxa (dabigatran etexilate mesilate) hard capsules (all strengths)

Section 4.4 of the SPC has been updated to include a warning regarding thromboembolic risk in patients with antiphospholipid syndrome.

<https://www.medicines.org.uk/emc/product/4703/smpc>

Prostap 3 DCS (11.25 mg leuprorelin acetate) Prostap SR DCS (3.75 mg leuprorelin acetate)

SPCs updated with new indications in advanced / early breast cancer. In the pre- and perimenopausal breast cancer setting, the initiation of aromatase inhibitor treatment before adequate ovarian suppression with leuprorelin has been achieved, has been added as a contraindication.

<https://www.medicines.org.uk/emc/product/4651/smpc>

Sinemet (levodopa/carbidopa) tablets– all strengths

The SPCs for Sinemet (10mg/100mg; 25mg/100mg and 25mg/250mg) have been updated with a change in the tablet description with respect to colour, shape and tablet markings.

<https://www.medicines.org.uk/emc/product/1654/smpc>

Utrogestan (progesterone) vaginal 200mg capsules

The SPC lists missed abortion as a contraindication to treatment. Vaginal discharge, vaginal haemorrhage and pruritus have been added as adverse events of unknown frequency.

<https://www.medicines.org.uk/emc/product/3244/smpc>

Victoza (liraglutide) 6 mg/ml solution for injection in pre-filled pen

SPC advises blood glucose self-monitoring to adjust dose of sulfonylurea and insulin, especially when liraglutide is started and insulin is reduced, using a stepwise approach. DKA has been reported in insulin-dependent patients after rapid discontinuation or dose reduction of insulin.

<https://www.medicines.org.uk/emc/product/6585/smpc>

Viridal Duo (alprostadil) preparations

The SPC now details that gastrointestinal haemorrhage is a potential adverse effect of treatment (frequency unknown). It warns that alprostadil should be used cautiously in patients with a history of gastrointestinal disease (e.g. ulcers) and in those taking antithrombotics.

<https://www.medicines.org.uk/emc/product/1452/smpc>