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Medicines Safety Assurance Tool December 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

Buccolam (midazolam) oromucosal solution pre-filled syringes

Medicines and Healthcare products Regulatory Agency | 07 Dec 2017

Shire has distributed the Direct Healthcare Professional Communication (DHCP) attached due to reports that the translucent tip-cap sometimes remains on the syringe tip when pulling the red cap off, as shown in the DHCP diagrams.

<https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-buccolam-midazolam-omomucosal-solution-pre-filled-syringes>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Eluxadoline (Truberzi ▼): risk of pancreatitis; do not use in patients who have undergone cholecystectomy or in those with biliary disorders

Medicines and Healthcare Products Regulatory Agency | 15 Dec 2017

Cases of pancreatitis, with or without sphincter of Oddi spasm, have been reported in patients taking eluxadoline. Some cases have resulted in hospitalisation and death, primarily in patients who have undergone cholecystectomy.

<https://www.gov.uk/drug-safety-update/eluxadoline-truberzi-risk-of-pancreatitis-do-not-use-in-patients-who-have-undergone-cholecystectomy-or-in-those-with-biliary-disorders>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Fingolimod (Gilenya ▼): new contraindications in relation to cardiac risk

Medicines and Healthcare Products Regulatory Agency | 15 Dec 2017

Fingolimod can cause persistent bradycardia, which can increase the risk of serious cardiac arrhythmias. New contraindications have been introduced for patients with pre-existing cardiac disorders.

<https://www.gov.uk/drug-safety-update/fingolimod-gilenya-new-contraindications-in-relation-to-cardiac-risk>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Fingolimod (Gilenya ▼): updated advice about risk of cancers and serious infections

Medicines and Healthcare Products Regulatory Agency | 15 Dec 2017

Monitor patients closely for skin cancers. Advise patients to seek urgent attention if they develop signs or symptoms of serious infections.

<https://www.gov.uk/drug-safety-update/fingolimod-gilenya-updated-advice-about-risk-of-cancers-and-serious-infections>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Mycophenolate: updated recommendations for contraception for men and women

European Medicines Agency | 15 Dec 2017

The European Medicines Agency has concluded that current evidence does not indicate a risk of malformations or miscarriages when the father has taken mycophenolate, although risk of genotoxicity cannot be completely ruled out.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/12/news_detail_002871.jsp&mid=WC0b01ac058004d5c1

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Which medicines should be considered for brand-name prescribing in primary care?

Specialist Pharmacy Services | 22 Dec 2017

There are some circumstances in which continuity of same product is important for patient safety and prescribing a specific manufacturer's product (brand or generic) is preferred. Q&A describes such situations and lists medicines that may be considered for brand-name prescribing.

<https://www.sps.nhs.uk/articles/which-medicines-should-be-considered-for-brand-name-prescribing-in-primary-care/>

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 | Dec 2017

Bydureon (exanatide) suspension for injection

The SPC has been updated with the addition of new clinical data for exenatide in combination with insulin.

<https://www.medicines.org.uk/emc/product/3650>

Duodopa (levodopa and 5 mg carbidopa) intestinal gel

Dopamine dysregulation syndrome has been added as a potential adverse effect of treatment (frequency unknown)

<http://www.medicines.org.uk/emc/medicine/20786>

Enbrel (etanercept) 25mg and 50 mg injection (all presentations)

The ADRs leukaemia; lymphoma; and peripheral demyelinating events have been added to SPC, which has also been updated with information about two ADRs, interstitial lung disease and autoimmune hepatitis.

Leukaemia; lymphoma; and peripheral demyelinating events have been added as potential adverse effects from treatment (frequency – rare)

<http://www.medicines.org.uk/emc/medicine/22143>

Esmya (ulipristal acetate) 5 mg Tablets

Drug hypersensitivity and angioedema have been added as potential adverse effects from treatment (uncommon and frequency unknown respectively)

<https://www.medicines.org.uk/emc/product/3951/smpc>

Lustral (sertraline) tablets – all strengths

Trismus, the inability to open the mouth fully, has been added as an adverse event (frequency unknown).

<https://www.medicines.org.uk/emc/product/2835/smpc>

Neupro (rotigotine) transdermal patch (all strengths)

Section 4.2 now advises that the patch should be pressed down firmly with the palm of the hand for about 30 seconds, so that it sticks well.

<http://www.medicines.org.uk/emc/medicine/31529>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Olumiant (baricitinib) patient alert card

This alert card has been produced by manufacturers for patients to keep to highlight to healthcare professionals that they are on this treatment. It highlights that it should not be used during pregnancy, and that infections are a known adverse effect of treatment.

<https://www.medicines.org.uk/emc/product/2434/rmms>

Piriteze Allergy 1mg/ml Syrup (cetirizine)

Sections 4.4 and 4.8 have been updated to advise that skin reactions such as urticaria and pruritus may occur after cetirizine is stopped.

<https://www.medicines.org.uk/emc/product/4132/smpc>

Saflutan (tafluprost) eye drops

Macular oedema has been added as a potential adverse effect of treatment (frequency unknown). SPC also now points out that tafluprost can cause hair growth in areas where it repeatedly comes into contact with the skin surface.

<http://www.medicines.org.uk/emc/medicine/31337>

Salofalk (mesalazine) tablets

Photosensitivity has been added as a rare potential adverse reaction to treatment.

<http://www.medicines.org.uk/emc/medicine/16914>

Seretide (fluticasone/salmeterol) Accuhaler – all strengths

The SPC has been updated to include an excipient warning for lactose monohydrate.

<https://www.medicines.org.uk/emc/product/5504/smpc>

Solian (amisulpiride) solution 100mg/ml

SPC now advises that co-administration of amisulpiride and clozapine may lead to an increase in plasma levels of amisulpiride

<http://www.medicines.org.uk/emc/medicine/25310>

Testogel (testosterone)

The SPC has been updated in line with PRAC recommendations on thrombophilia risk, which advise caution, following post-marketing studies and reports of thrombotic events in patients during testosterone therapy

<https://www.medicines.org.uk/emc/product/6808/smpc>

Topamax (topiramate)

Before initiating topiramate in a woman of childbearing potential, pregnancy testing should be performed and a highly effective contraceptive method advised. The patient should be fully informed of the risks related to the use of topiramate during pregnancy.

<https://www.medicines.org.uk/emc/product/1974/smpc>

Viagra Connect (sildenafil)

This new product, for use in adult men with erectile dysfunction, is available from pharmacies over the counter following discussion with a pharmacist.

<http://www.medicines.org.uk/emc/medicine/34411>

Zidoval (metronidazole) vaginal gel

Urticaria has been added as a potential adverse effect of treatment (frequency unknown).

<http://www.medicines.org.uk/emc/medicine/28>