Medicines Safety Assurance Tool

June 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

MIDLANDS AND LANCASHIRE COMMISSIONING SUPPORT UNIT

Brimonidine gel (Mirvaso): risk of systemic cardiovascular effects; not to be applied to damaged skin

MHRA | 21-June-2017

- cases of bradycardia, hypotension (including orthostatic hypotension), and dizziness after application of brimonidine gel have been reported, some of which required hospitalisation
- some cases were associated with application of brimonidine gel after laser procedures to the skin, which possibly caused increased absorption of the gel
- warn patients not to apply brimonidine gel to irritated or damaged skin, including after laser therapy to the skin

Proposed action

- [x] Newsletter
- [x] Optimise Rx/ScriptSwitch
- [ ] Practice audit/search
- [ ] Other

Action taken

Status: Unassigned

https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-systemic-cardiovascular-effects-not-to-be-applied-to-damaged-skin

Date completed

Denosumab (Prolia, Xgeva▼): reports of osteonecrosis of the external auditory canal

MHRA | 21-June-2017

- the possibility of osteonecrosis of the external auditory canal should be considered in patients receiving denosumab who present with ear symptoms including chronic ear infections or in those with suspected cholesteatoma
- possible risk factors include steroid use and chemotherapy, with or without local risk factors such as infection or trauma
- advise patients to report any ear pain, discharge from the ear, or an ear infection during denosumab treatment
- report cases of osteonecrosis of any bone suspected to be associated with denosumab or any other medicine on a Yellow Card

Proposed action

- [x] Newsletter
- [ ] Optimise Rx/ScriptSwitch
- [ ] Practice audit/search
- [ ] Other

Action taken

Status: Unassigned

https://www.gov.uk/drug-safety-update/denosumab-prolia-xgeva-reports-of-osteonecrosis-of-the-external-auditory-canal

Date completed

e-cigarettes and refill containers (e-liquids): report suspected side effects and safety concerns

MHRA | 21-June-2017

Members of the public and healthcare professionals can use the Yellow Card Scheme website to report any suspected side effects or safety concerns with e-cigarettes and the e-liquids used for vaping.
These issues could include:

- suspected side-effects that occurred after the use of e-cigarettes and e-liquids
- harm to children or non-users, including accidental poisoning
- safety issues or defects with e-cigarette devices

Proposed action

- [x] Newsletter
- [ ] Optimise Rx/ScriptSwitch
- [ ] Practice audit/search
- [ ] Other

Action taken

Status: Unassigned

https://www.gov.uk/drug-safety-update/e-cigarettes-and-refill-containers-e-liquids-report-suspected-side-effects-and-safety-concerns

Date completed

Influenza Season 2016/17: Use of Antiviral Medicines

CAS | 12-Jun-2017

Prescribers working in primary care and community pharmacists should no longer prescribe or supply antiviral medicines for the prophylaxis and treatment of influenza on an FP10 prescription form

Proposed action

- [x] Newsletter
- [x] Optimise Rx/ScriptSwitch
- [ ] Practice audit/search
- [ ] Other

Action taken

Status: Unassigned

https://www.cas.dh.gov.uk/ViewAndAcknowledgment/viewAttachment.aspx?Attachment_id=102782

Date completed

Risk minimisation materials: Physician prescribing checklist for Mysimba (8mg naltrexone /90mg bupropion) prolonged-release tablets

electronic Medicines Compendium | 14-Jun-2017

This checklist ensures the appropriate contraindications and special warnings/precautions are considered when prescribing Mysimba prolonged-release tablets.

Proposed action

- [x] Newsletter
- [ ] Optimise Rx/ScriptSwitch
- [ ] Practice audit/search
- [ ] Other

Action taken

Status: Unassigned

Date completed

http://www.medicines.org.uk/emc/RMM.886.pdf

Risk management materials for Valdoxan® (agomelatine) - liver function monitoring and drug interactions

electronic Medicines Compendium | 19-Jun-2017

New guidance for healthcare professionals has been provided for monitoring liver function in patients before and during treatment with Valdoxan. Concomitant use of potent CYP1A2 inhibitors (e.g. fluvoxamine, ciprofloxacin) is also contraindicated with Valdoxan.

Proposed action

- [x] Newsletter
- [ ] Optimise Rx/ScriptSwitch
- [ ] Practice audit/search
- [ ] Other

Action taken

Status: Unassigned

Date completed

http://www.medicines.org.uk/emc/RMM.64.pdf

Educational Risk Minimisation Materials: Prescribers' Administration Guide for Qutenza®

electronic Medicines Compendium | 22-Jun-2017

Prescribers should refer to this administration guide before administering Qutenza. It covers warnings and precautions for use, practice precautions, briefing the patient, correct application of patch, managing treatment-associated discomfort, and patient follow-up.

http://www.medicines.org.uk/emc/RMM.558.pdf

Proposed action

- [x] Newsletter
- [ ] Optimise Rx/ScriptSwitch
- [ ] Practice audit/search
- [ ] Other

Action taken

Status: Unassigned

Date completed

Summary of Product Characteristics Updates

electronic Medicines Compendium | Jun-2017

Revised SPC: Ganfort® (bimatoprost and timolol) preparations

The adverse events of asthma exacerbation and chronic obstructive pulmonary disease (COPD) exacerbation have been added to section 4.8.

http://www.medicines.org.uk/emc/medicine/28209

Revised SPC: Zocor® (simvastatin) tablets

Simvastatin should now not be used within 7 days of stopping fusidic acid as well as avoiding concomitant administration. Also, simvastatin dose adjustments should be considered in concomitant administration of Breast Cancer Resistant Protein inhibitors (eg elbasvir, grazoprevir)

http://www.medicines.org.uk/emc/medicine/1201

Revised SPC: Reminyl® (galantamine) – all presentations

Complete atrioventricular block is now listed as a rare adverse reaction.

http://www.medicines.org.uk/emc/medicine/10335

Proposed action

- [x] Newsletter
- [ ] Optimise Rx/ScriptSwitch
- [ ] Practice audit/search
- [ ] Other

Action taken

Status: Unassigned

Date completed

Revised SPC: Simvastatin Rosemont 20mg/5ml and 40mg/5ml Oral Suspension
Section 4.2 now advises that simvastatin Rosemont oral suspension is suitable for administration via nasogastric or percutaneous endoscopic gastrostomy tubes.
http://www.medicines.org.uk/emc/medicine/32577

Revised SPC: Actiq® (fentanyl) Lozenges
The SPC now states use in those aged <16 years is not recommended. Additional side-effects listed/discussed include adrenal insufficiency, androgen deficiency, neonatal withdrawal syndrome and anaphylaxis and hypersensitivity.
http://www.medicines.org.uk/emc/medicine/30554

Revised SPC: Losec® (omeprazole) – all formulations
Section 4.8 has been updated with a new adverse effect - benign fundic gland polyps (frequency common).
http://www.medicines.org.uk/emc/medicine/7275

Revised SPC: Neoclarityn® (desloratadine) – all formulations
Section 4.4 contains information on administration in patients with medical/familial history of seizure and discontinuation in patients who experience a seizure. Section 4.8 has been updated with abnormal behaviour and aggression as potential adverse events (frequency unknown).
http://www.medicines.org.uk/emc/medicine/9290

Revised SPCs: Solu-Medrone® (methylprednisolone) preparations
Sections 4.4 and 4.5 have been revised to include warnings concerning co-treatment with CYP3A inhibitors (including cobicistat-containing products), which is expected to increase the risk of systemic side-effects. The combination should be avoided unless benefit outweighs risk.
http://www.medicines.org.uk/emc/medicine/27656

Revised SPC: Pevanti® (prednisolone) tablets
SPC highlights that visual disturbance may occur with corticosteroids. If blurred vision or other visual disturbances occur, the patient should be considered for referral to an ophthalmologist. Possible causes may include cataract, glaucoma or central serous chorioretinopathy.
http://www.medicines.org.uk/emc/medicine/30012

Revised SPC: DuoResp Spiromax® (budesonide/formoterol) inhalation powder
Sections 4.4 and 4.8 note that visual disturbance may occur with corticosteroids.If blurred vision or other visual disturbances occur, the patient should be considered for referral to an ophthalmologist Possible causes may include cataract, glaucoma or central serous chorioretino
http://www.medicines.org.uk/emc/medicine/29187

Revised SPC: Brevinor® (norethisterone/ethinylestradiol) Tablets
SPC has been updated with information on interaction between combined hormonal contraceptives containing ethinylestradiol with products containing ombitasvir/paritaprevir/ritonavir (Viekirax) and dasabuvir with or without ribavirin, which may increase risk of ALT elevations.
http://www.medicines.org.uk/emc/medicine/1899

Revised SPC: Symbicort® (budesonide/formoterol) Turbohaler Inhalation powder (all strengths)
The storage restriction has been removed from SPC. Previously it had advised that device should not be stored at temperatures above 30 degrees and that the container should be kept tightly closed to guard against development of moisture.
http://www.medicines.org.uk/emc/medicine/4820

Revised SPC: Nexium® (esomeprazole) preparations
Fundic gland polyps (benign) has been added as an undesirable effect.
http://www.medicines.org.uk/emc/medicine/24695

Revised SPC: Qtern® (saxagliptin and dapagliflozin) 5 mg/10 mg film-coated tablets
Section 4.4 now notes that an increase in cases of lower limb amputation (primarily of the toe) has been observed in ongoing long-term, clinical studies with another SGLT2 inhibitor. It is unknown whether this constitutes a class effect.
http://www.medicines.org.uk/emc/medicine/32750

Revised SPC: Avodart® (dutasteride) 0.5mg soft capsules
Sections 4.4 and 5.1 of SPC have been updated with data from trials or reports during post-marketing period, about the risk of prostate and male breast cancer, and heart failure.
http://www.medicines.org.uk/emc/medicine/11618

Revised SPC: Eperzan® (albiglutide) powder and solvent for solution for injection
This SPC now advises that dehydration, sometimes leading to renal impairment and acute renal failure, has been reported in patients treated with albiglutide. Patients should be advised of this risk and advised to take precautions to avoid fluid depletion
http://www.medicines.org.uk/emc/medicine/31399

Revised SPC: Lumigan® (bimatoprost) 0.1mg/ml
Eye discharge, increased lacrimation, eye oedema and foreign body sensation in the eyes have been added as potential adverse effects of treatment (frequency unknown)
http://www.medicines.org.uk/emc/medicine/22807

Revised SPC: Trulicity® (dulaglutide) solution for injection
Angioedema has been added as a rare potential adverse effect of treatment.
http://www.medicines.org.uk/emc/medicine/29747

Revised SPC: Combodart (0.5 mg dutasteride/0.4 mg tamsulosin) hard capsules
Sections 4.4 and 5.1 of SPC have been updated with data from trials or reports during post-marketing period, about the risk of prostate and male breast cancer, and heart failure with dutasteride.
http://www.medicines.org.uk/emc/medicine/22943

Revised SPC: Intuniv (guanfacine) 1 mg, 2 mg, 3 mg, 4 mg prolonged-release tablets
Erectile dysfunction has been added to SPC as an undesirable effect of unknown frequency.
http://www.medicines.org.uk/emc/medicine/31294

Revised SPC: Xgeva® (denosumab)
SPC updated to warn osteonecrosis of external auditory canal has been reported with denosumab. This should be considered in patients with ear symptoms including chronic ear infections. Risk factors include steroids and chemotherapy and/or local risk factors, e.g. infection/trauma
http://www.medicines.org.uk/emc/medicine/24755

Revised SPC: NovoRapid 100 units/ml in a vial, NovoRapid Penfill 100 units/ml, NovoRapid FlexPen 100 units/ml,

The storage information for NovoRapid FlexPen/NovoRapid FlexTouch has been updated to say that it can be stored in a refrigerator (previously stated that it should not be refrigerated). [Information for NovoRapid vial/NovoRapid Penfill and NovoRapid PumpCart remains unchanged].

http://www.medicines.org.uk/emc/medicine/25033