Medicines Safety Assurance Tool

July 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

Risk of death and severe harm from ingestion of superabsorbent polymer gel granules

Central Alerting System | 05-July-2017

Superabsorbent polymer gel granules are widely used in health and social care, typically as small sachets placed in urine and vomit bowls. If the gel granules are put in the mouth they expand on contact with saliva risking airway obstruction. This has happened where patients have mistaken the sachets for sweets, or sugar or salt packets, but some incident reports also describe attempts of deliberate self-harm. Healthcare providers are asked to review their overall approach to using these products.
https://www.cas.dh.gov.uk/ViewAndAcknowledgment/viewAttachment.aspx?Attachment_id=102798

Proposed action

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

Action taken

Status: Unassigned

Date completed

Important safety information for people with diabetes using NovoPen® Echo® or NovoPen® 5

Novo Nordisk | 05-July-2017

The insulin cartridge holder used in some batches of NovoPen Echo and NovoPen 5 may crack or break if exposed to certain chemicals (e.g. household cleaning agents). Patients should check their device and contact the manufacturer for replacement if it belongs to an affected batch.
http://offlinehbpl.hbpl.co.uk/NewsAttachments/2MM/170705-Important-safety-information-for-people-with-diabetes-using-NovoPen-Echo-or-NovoPen-5.pdf

Proposed action

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

Action taken

Status: Unassigned

Date completed

Clexane (enoxaparin sodium)

Sanofi |June-2017

Updates to strength expression, dose regimens in DVT/PE, use in patients with severe renal impairment
https://assets.publishing.service.gov.uk/media/596f669a40f0b60a400001ba/Clexane_DHPC_300617.pdf

Proposed action

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

Action taken

Status: Unassigned

Date completed

The safer management of controlled drugs

Care Quality Commission | 27-July-2017

Prescribers must make sure that they review patients regularly, depending on their clinical need. This is to ensure that the prescribed controlled drugs and length of treatment continues to be the most appropriate for their condition and to reduce opportunities for over prescribing and diversion.
http://www.cqc.org.uk/sites/default/files/20170718_controlleddrugs2016_report.pdf

Proposed action

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

Action taken

Status: Unassigned

Date completed

Epilim (sodium valproate) risk management material

Sanofi UK | July-2017

This poster, to be displayed in dispensaries of pharmacies warns that valproate should only be used in girls, women of child bearing age and those who are pregnant or planning pregnancy, when other treatments are ineffective or not tolerated. http://www.medicines.org.uk/emc/RMM.1002.pdf

Sanofi has issued letters for specialists and specialist nurses/midwives, GPs and pharmacists advising that valproate medicines should be used only when no other treatment is effective or tolerated in girls, women of childbearing age, and women who are pregnant/planning pregnancy.
http://www.medicines.org.uk/emc/medicine/23020#rmm

Proposed action

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

Action taken

Status: Unassigned

Date completed

Glucose content of Lucozade Energy drinks reduced by 50% from April 2017

Royal Pharmaceutical Society of Great Britain | 30-March-2017

People with diabetes who consume Lucozade Energy Original for the treatment of hypoglycaemia should be advised to check the label of any product purchased to ensure that they are aware of the correct quantity to consume.
http://www.medicinesresources.nhs.uk/en/Medicines-Awareness/Safety-Alerts/Safety-alerts/Glucose-content-of-Lucozade-Energy-drinks-to-be-reduced-by-50-from-April-2017/

Proposed action

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

Action taken

Status: Unassigned

Date completed

Summary of Product Characteristics Update

July-2017

Alecensa (alectinib) 150 mg Hard Capsules
SPC updated with information about reports of increased alkaline phosphatase in the post-marketing period. Cases were also reported in pivotal Phase II clinical trials NP28761 and NP28673. This has been added to SPC as a common adverse effect.
http://www.medicines.org.uk/emc/medicine/33005

Alprolix (eftrenonacog alfa) powder and solvent for solution for injection
The SPC now states that some patients who are well-controlled on a once every 10 days regimen might be treated on an interval of 14 days or longer. Side-effects of FIX inhibitor development and hypersensitivity (observed in post-marketing experience) have been added.
http://www.medicines.org.uk/emc/medicine/32153

Anoro Ellipta (55 micrograms umeclidinium /22 micrograms vilanterol) inhalation powder, pre-dispensed
Dysphonia (voice disorder) has been added to SPC as adverse reaction of uncommon frequency.
http://www.medicines.org.uk/emc/medicine/28949

Atriance (nelarabine) 5 mg/ml solution for infusion
SPC updated to warn that patients treated with nelarabine are potentially at risk of suffering from somnolence during and for several days after treatment therefore they should be warned that somnolence can affect performance of skilled tasks, such as driving.
http://www.medicines.org.uk/emc/medicine/20045

Aubagio (teriflunomide) 14 mg film-coated tablets
SPC now warns measurement of ionised calcium (IC) levels might show falsely decreased values under treatment with leflunomide and/or teriflunomide (metabolite) depending on type of IC analyser used. In case of doubt, total albumin adjusted serum calcium level should be measured.
http://www.medicines.org.uk/emc/medicine/28533

Bexsero Meningococcal Group B vaccine for injection in pre-filled syringe
The SPC now notes that reported injection site reactions include extensive swelling of the vaccinated limb and injection site nodule.
http://www.medicines.org.uk/emc/medicine/28407

Proposed action

- [x] Newsletter
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Action taken

Status: Unassigned

Date completed

Canesten products containing fluconazole
SPCs for fluconazole products have been updated with data from study suggesting increased risk of spontaneous abortion in women treated with it in 1st trimester. It should not be used during pregnancy/in women of childbearing potential unless adequate contraception is used.
http://www.medicines.org.uk/emc/medicine/13959

Copaxone (glatiramer acetate) Injection, Pre-filled Syringe
Glatiramer is no longer contraindicated in pregnancy. Current data indicate no malformative or feto/neonatal toxicity, however no relevant epidemiological data are available. It is preferable to avoid the use during pregnancy unless the benefit to the mother outweighs the risk to
http://www.medicines.org.uk/emc/medicine/30795

Daktarin (miconazole) Oral Gel
SPC has been updated to advise increases in INR and bleeding events have been reported in patients on oral anticoagulants and miconazole (MC) oral gel. MC is systemically absorbed and is known to inhibit CYP2C9 and CYP3A4 which can lead to prolonged effects of warfarin.
http://www.medicines.org.uk/emc/medicine/7301

Desferal (desferrioxamine mesilate) vials
Shelf life has increased from 18 to 36 months and storage conditions have changed from above 30ºC to above 25ºC.
http://www.medicines.org.uk/emc/medicine/2666

Dysport (botulinum type A toxin) 300U and 500U
SPC has been updated with new indication of axillary hyperhidrosis.
http://www.medicines.org.uk/emc/medicine/32114

Eperzan (albiglutide) 30 mg and 50 mg powder and solvent for solution for injection
SPC now notes dehydration, sometimes leading to renal impairment and acute renal failure, has been reported and has occurred in patients without gastrointestinal side effects. Patients should be advised of this potential risk and take precautions to avoid fluid depletion.
http://www.medicines.org.uk/emc/medicine/31399

Evorel (estradiol) 25, 50, 75 & 100 patches
Section 4.2 advises on the addition of approved oral progestogens (eg oral norethisterone, 1mg/day or medroxyprogesterone acetate, 2.5mg/day), either on a cyclical or continuous basis for women with an intact uterus for the prevention of adverse endometrial effects.
http://www.medicines.org.uk/emc/medicine/7235

Evra (norelgestromin/ ethinyl estradiol) transdermal patch
Sections 4.3, 4.4 and 4.5 include a contraindication for patients receiving drug combinations with ombitasvir/paritaprevir/ritonavir and dasabuvir, with or without ribavirin. Concomitant use may increase the risk of ALT elevations.
http://www.medicines.org.uk/emc/medicine/12124

Foscavir (foscarnet) 24 mg/ml Solution for Infusion
Number of adverse events added, including hypersensitivity, dehydration, tachycardia, gastrointestinal haemorrhage, urticaria, angioedema, proteinuria, haematuria, erythema multiforme, toxic epidermal necrolysis, Stevens Johnson syndrome, glomerulonephritis and nephrotic syndrome
http://www.medicines.org.uk/emc/medicine/174

Gilenya (fingolimod) 0.5mg hard capsules
Before initiation of fingolimod, in women of childbearing potential, a negative pregnancy test result needs to be available. Counsellingshould be provided regarding the potential for serious risk to the foetus and the need for effective contraception during treatment.
http://www.medicines.org.uk/emc/medicine/24443

Imodium (loperamide) 1 mg/5 ml oral solution
SPC has been updated to warn that cardiac events including QT prolongation and torsades de pointes have been reported in association with overdose. Some cases had a fatal outcome. Patients should not exceed recommended dose and/or recommended duration of treatment.
http://www.medicines.org.uk/emc/medicine/17607

Incruse (umeclidinium) 55 micrograms inhalation powder, pre-dispensed
Eye pain (rare frequency) and increased intraocular pressure (unknown frequency) have been added to SPC as adverse effects.
http://www.medicines.org.uk/emc/medicine/29394

Komboglyze (saxagliptin, metformin) 2.5mg-850mg & 2.5mg-1000mg Tablets
Information on 'saxagliptin add on to dapagliflozin plus metformin therapy' and 'saxagliptin and dapagliflozin add on to metformin therapy' has been added to section 5.1 and the indication rewritten to incorporate this updated information.
http://www.medicines.org.uk/emc/medicine/27311

Lioresal (baclofen) – all formulations
Sections 4.4, 4.6 and 4.8 include additional information on drug withdrawal symptoms in neonates exposed to intrauterine levels of baclofen. Onset of scoliosis or worsening of pre-existing scoliosis has been reported in patients treated specifically with Lioresal Intrathecal.
http://www.medicines.org.uk/emc/medicine/4113

Lyrica (pregabalin) capsules
Hepatobiliary disorders have been added to section 4.8. Adverse effects include elevated liver enzymes (uncommon), jaundice (rare) and hepatic failure/hepatitis (very rare).
http://www.medicines.org.uk/emc/medicine/14651

Mirvaso (brimonidine) 3mg/g Gel
SPC now highlights that brimonidine gel should not be applied to irritated skin after laser surgery. Bradycardia (rare) and dizziness (uncommon) have been added as potential adverse effects of treatment.
http://www.medicines.org.uk/emc/medicine/28682

MST (morphine sulphate) Continus tablets 5 mg, 10 mg, 15 mg, 30 mg, 60 mg, 100 mg, 200 mg
Pneumonia aspiration has been added to the list of symptoms of overdose.
http://www.medicines.org.uk/emc/medicine/1223

One-Alpha Drops (alfacalcidol)
In section 6.1 (List of excipients), dl-a-tocopherol is renamed to All-rac-a-tocopherol. The in use shelf life of the product has been changed from 28 days to 4 months.
http://www.medicines.org.uk/emc/medicine/3352

Onglyza (saxagliptin) 2.5mg & 5mg film-coated tablets
Information has been added to section 5.1 on 'saxagliptin add on to dapagliflozin plus metformin therapy' and on 'saxagliptin and dapagliflozin added on to metformin therapy'.
http://www.medicines.org.uk/emc/medicine/22315

ORENCIA (abatacept) 125 mg solution for injection (pre-filled syringe)
ORENCIA, alone or in combination with methotrexate (MTX), is licensed for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy including MTX has been inadequate, and for whom additional systemic therapy is not required.
http://www.medicines.org.uk/emc/medicine/27216

Prolia (denosumab)
Osteonecrosis of the external auditory canal (frequency unknown) has been reported with denosumab. Possible risk factors include steroid use and chemotherapy and/or local risk factors such as infection or trauma. SPC has been updated with information relating to when to re-evalaute patients after long term treatment and risk of adverse outcomes such as osteonecrosis of the jaw and atypical femur fractures.
SPC has been updated to include advice about long-term use: Optimal total duration of antiresorptive treatment for osteoporosis (incl both denosumab and bisphosphonates) has not been established. The need for continued treatment should be re-evaluated particularly after >5 yrs.
http://www.medicines.org.uk/emc/medicine/23127

Propecia (finasteride) 1mg tablets
Section 4.4 includes a new warning statement under a new sub-heading of 'Mood alterations and depression' to reflect that cases of depression, mood alterations and suicidal ideation have been reported. Section 4.8 has also been updated to include this information.
http://www.medicines.org.uk/emc/medicine/3680

Renvela (Sevelamer carbonate) powder for oral suspension
The SPC has been updated to highlight the licence extension for use in children and adolescents (>6 years of age and a body surface area (BSA) of ≥0.75m2).
http://www.medicines.org.uk/emc/medicine/22782

Revestive (teduglutide)
SPC highlights that a 1.25 mg strength vial is available for paediatric use (patients with a body weight <20 kg). Also, it is strongly recommended that the name and lot number of the product are recorded on each administration.
http://www.medicines.org.uk/emc/medicine/29315

Sebivo (telbivudine) 600mg film-coated tablets
Rare post-marketing cases of lactic acidosis (LA) have been reported with telbivudine; more often secondary to other serious conditions. Treatment should be discontinued when metabolic/LA of unknown aetiology occurs. Benign digestive symptoms may be indicative of LA development.
http://www.medicines.org.uk/emc/medicine/19740

Selincro (nalmefene) 18mg film-coated tablets
Section 4.7 has been amended and now notes that due to the possible occurrence of a number of adverse effects, nalmefene may have minor to moderate influence on the ability to drive and use machines and patients should exercise caution particular when starting treatment.
http://www.medicines.org.uk/emc/medicine/27609

Silkis (calcitriol) 3 micrograms per g ointment
The SPC now advises that caution must be used in patients receiving medications known to increase the serum calcium level, e.g. thiazide diuretics, or medications with pharmacological effects impacted by a change in calcium levels such as digoxin.
http://www.medicines.org.uk/emc/medicine/8621

Strensiq (asfotase) injection
SPC now highlights that treating physicians should inform a testing lab that a patient is being treated with asfotase when ordering samples. Alkaline Phosphatase is a detection reagent in many assays, and if asfotase alfa is present aberrant values could be reported
http://www.medicines.org.uk/emc/medicine/30861

Tivicay (dolutegravir) film-coated tablets
The shelf-life of Tivicay 10mg, 25mg, and 50mg tablets has been extended from 3 to 5 years, from 3 to 4 years and from 2 to 5 years respectively.
http://www.medicines.org.uk/emc/medicine/28545

Uptravi (selexipag)
Sections 4.3, 4.4 and 4.5 have been updated with information on the concomitant use of strong inhibitors of CYP2C8.
http://www.medicines.org.uk/emc/medicine/31963

Xagrid (anagrelide) 0.5mg hard capsule
SPC now warns that cases of pulmonary hypertension have been reported in patients treated with anagrelide. Patients should be evaluated for signs and symptoms of underlying cardiopulmonary disease prior to initiating and during anagrelide therapy.
http://www.medicines.org.uk/emc/medicine/15737

Xarelto (rivaroxaban) film coated tablets (all strengths)
Serious skin reactions, including Stevens-Johnson syndrome/Toxic Epidermal Necrolysis, have been reported. The highest risk appears to be early in the course of therapy. Treatment should be discontinued at the first appearance of a severe skin rash
http://www.medicines.org.uk/emc/medicine/21265

Xtandi (enzalutamide) 40mg capsules
Addition of seizure related information to sections 4.4/4.8. Caution should be used in patients with a history of seizures or other predisposing factors. Risk of seizure may be increased in patients receiving concomitant medicines that lower seizure threshold.
http://www.medicines.org.uk/emc/medicine/27912

Xultophy 100 units/ml insulin degludec + 3.6 mg/mL liraglutide solution for injection in a pre-filled pen
Use in hepatic impairment (HI) has been revised to state that Xultophy can be used in mild or moderate HI and glucose monitoring is to be intensified and dose adjusted on individual basis. Due to liraglutide component, it is not recommended for use in severe HI.
http://www.medicines.org.uk/emc/medicine/29493

Zometa (zoledronic acid) 4mg/100ml Solution for Infusion
Section 4.4 and 4.8 have been updated with new information on osteonecrosis of the external auditory canal (bisphosphonate class adverse reaction, frequency, very rare) and other anatomical sites including femur and hip (frequency, very rare).
http://www.medicines.org.uk/emc/medicine/25058

Zometa (zoledronic acid) 4mg/5ml Concentrate for Solution for Infusion

SPC revised to warn osteonecrosis (ON) of external auditory canal has been reported with bisphosphonates, mainly linked to long-term therapy. There have also been sporadic reports of ON of other sites, including hip/femur, mainly in adult cancer patients treated with Zometa.

http://www.medicines.org.uk/emc/medicine/14062