Medicines Safety Assurance Tool

July 2019

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

NHS
Midlands and Lancashire
Commissioning Support Unit

Febuxostat (Adenuric): increased risk of cardiovascular death and all-cause mortality in clinical trial in patients with a history of major cardiovascular disease

Medicines and Healthcare products Regulatory Agency | 18 July 2019

Avoid treatment with febuxostat in patients with pre-existing major cardiovascular disease (for example, myocardial infarction, stroke, or unstable angina), unless no other therapy options are appropriate.
https://www.gov.uk/drug-safety-update/febuxostat-adenuric-increased-risk-of-cardiovascular-death-and-all-cause-mortality-in-clinical-trial-in-patients-with-a-history-of-major-cardiovascular-disease

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Rivaroxaban (Xarelto▼): reminder that 15 mg and 20 mg tablets should be taken with food

Medicines and Healthcare products Regulatory Agency | 18 July 2019

MHRA has received a small number of reports suggesting lack of efficacy (thromboembolic events) in patients taking 15 mg or 20 mg rivaroxaban on an empty stomach; remind patients to take 15 mg or 20 mg rivaroxaban tablets with food.
https://www.gov.uk/drug-safety-update/rivaroxaban-xarelto-reminder-that-15-mg-and-20-mg-tablets-should-be-taken-with-food

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Direct Acting Oral Anticoagulants (DOACs) in Renal Impairment: Practice Guide to Dosing Issues

Specialist Pharmacy Service | 24 July 2019

Choosing the correct dose of an anticoagulant is important to ensure that the patient receives the benefits of reduction of thrombo-embolic events whilst minimising the risk of adverse bleeding events. The paper focuses on the use of DOACs in patients with atrial fibrillation and provides case study examples from current clinical practice. It is intended as a practice aid, not national guidance, and is particularly suitable for new or less experienced practitioners working in primary care.
https://www.sps.nhs.uk/articles/direct-acting-oral-anticoagulants-doacs-in-renal-impairment-practice-guide-to-dosing-issues/

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Fmd Alert Class 2, Action Within 48 Hours, Kosei Pharma Uk Ltd, Mpt Pharma Ltd, Doncaster Pharmaceuticals Group Ltd and Drugsrus Ltd / P.I.E. Pharma Ltd

Central Alerting System | 25 July 2019

Recall of medicines that have been taken out of the regulated medicines supply chain during distribution and later re-introduced. The products were parallel imported into the UK from Italy and re-labelled in Kosei Pharma UK Ltd, MPT Pharma Ltd, Doncaster Pharmaceuticals Group Ltd and Drugsrus Ltd / P.I.E. Pharma Ltd. The products are believed to be legitimate medicines.
https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102883

Proposed action

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

Action taken

Status: Unassigned | Action due date | Date completed

Summary of Product Characteristics Update

Electronic Medicines Compendium | July 2019

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status: Unassigned | Action due date | Date completed

Actiq (fentanyl) Lozenges

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

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

Biquelle (quetiapine fumarate) XL 200mg prolonged-release tablets

SPC now warns of increased risk of self-harm and suicide in patients aged 25 to 64 years without history of self-harm and increased risk of death in patients with Parkinson's aged > 65 years. Stroke was added as undesirable effect of unknown frequency.

https://www.medicines.org.uk/emc/product/3612/smpc

Brintellix (vortioxetine) tablets – all strengths

Sections 4.4 and 4.8 of the SPC has been updated to advise that anaphylactic reaction, haemorrhage, and rash with a frequency not known have been reported with vortioxetine.

https://www.medicines.org.uk/emc/product/10443/smpc

Clipper (beclomethasone) sustained release tablets

Blurred vision and hiccups have been added as potential adverse effects of treatment (frequency = rare) to the SPC

https://www.medicines.org.uk/emc/product/6417/smpc

Eliquis (apixaban) film-coated tablets

The SPC has been updated to include information about dosing in patients undergoing interventions (e.g. catheter ablation) for non-valvular atrial fibrillation.

https://www.medicines.org.uk/emc/product/2878/smpc

Epilim Chrono tablets (sodium valproate)

Section 4.2 of the SPC now advises that Epilim Chrono may be given once or twice daily. The tablets should be swallowed whole and not crushed or chewed.

https://www.medicines.org.uk/emc/product/3979/smpc

Hydrea (hydroxycarbamide) 500mg hard capsules
The drug is now licensed for treatment of chronic myeloid leukaemia. Section 4.8 of the SPC has been updated to include the following adverse reactions: pneumonitis, alveolitis, allergic alveolitis, and cough.
https://www.medicines.org.uk/emc/product/271/smpc

Iglu Gel and Iglu Rapid Relief Gel (lidocaine hydrochloride, aminoacridine hydrochloride)
The SPC now advises "it is very important that a doctor/dentist is consulted where an unexplained mouth ulcer lasts > 3 weeks or keeps coming back. This is to exclude the rare possibility of oral cancer, which can benefit from early diagnosis and treatment".
https://www.medicines.org.uk/emc/product/6230/smpc

Ikervis (ciclosporin) 1 mg/mL eye drops, emulsion
Ocular/peri-ocular malignancies/premalignant conditions have been added to SPC as contraindications. SPC now warns co-administration with steroid eye drops may potentiate effects on immune system. Regular examination of eye(s) is now recommended when Ikervis is used for years.
https://www.medicines.org.uk/emc/product/6937/smpc

Innovace (enalapril) tablets – all strengths
Sections 4.4 and 4.5 of the SPC have been updated to include information related to trimethoprim-containing products such as cotrimoxazole and other drugs that may increase serum potassium – caution and frequent monitoring of potassium is advised in case of concomitant use.
https://www.medicines.org.uk/emc/product/10543/smpc

Innozide (enalapril/hydrochlorothiazide) 20/12.5 mg Tablets
Sections 4.4 and 4.5 of the SPC have been updated to include information related to trimethoprim-containing products such as cotrimoxazole and other drugs that may increase serum potassium – caution and frequent monitoring of potassium is advised in case of concomitant use.
https://www.medicines.org.uk/emc/product/1007

Jaydess (levonorgestrel) 13.5mg intrauterine delivery system
Various sections of the SPC have been updated to include information about sepsis, hypersensitivity reactions and the final report of the 5-year follow-up of the EURAS-IUD study which evaluated perforation risk.
https://www.medicines.org.uk/emc/product/5297/smpc

Moventig (naloxegol) film-coated tablets
Sections 4.4 and 4.8 of the SPC now advise naloxegol must not be used in those with known or suspected GI obstruction or in patients at increased risk of recurrent obstruction, or in patients with underlying cancer who are at heightened risk of GI perforation.
https://www.medicines.org.uk/emc/product/10427/smpc

Mysimba 8 mg/90 mg (naltrexone/buprenorphine) prolonged-release tablets
Sections 4.7 and 4.8 advise use of naltrexone/bupropion has been associated with somnolence and episodes of loss of consciousness, sometimes caused by seizure. Patients must be advised to exercise caution while driving or operating machines during treatment.
https://www.medicines.org.uk/emc/product/2684/smpc

Palexia (tapentadol) Oral Solution 20 mg/ml
SPC has been revised to advise that this product is not recommended for children with a body weight of 16 kg or less due to the high concentration of tapentadol.
https://www.medicines.org.uk/emc/product/5346/smpc

Paroven (oxerutins) 250 mg Capsules
The SPC has been updated to advise safety and efficacy of oxerutins (Paroven) in children and adolescents aged less than 18 years has not yet been established, and therefore lower age limit has been changed from 12 years to 18 years.
https://www.medicines.org.uk/emc/product/1028

Reltebon (oxycodone hydrochloride) Prolonged-release Tablets (all strengths)
SPCs updated to caution against concomitant administration of oxycodone with serotonin agents e.g. selective serotonin re-uptake inhibitors; which may cause serotonin toxicity. Oxycodone dosage may need to be reduced in patients using these medications.
https://www.medicines.org.uk/emc/product/5366/smpc

Solian (amisulpride) – all presentations
Section 4.6 of the SPC advises there are limited data on amisulpride in pregnant women - safety of use during human pregnancy has not been established. Amisulpride is excreted into breastmilk in rather large amounts above the accepted value of 10% of the maternal weight-adjusted dosage.
https://www.medicines.org.uk/emc/product/4892/smpc

Xarelto (rivaroxaban) tablets
SPC now advises that rivaroxaban should not be used for thromboprophylaxis in patients having recently undergone transcatheter aortic valve replacement as the safety and efficacy have not been studied in this population.
https://www.medicines.org.uk/emc/product/6402/smpc

Xultophy (insulin degludec and liraglutide) HealthCare Professional Brochure
This brochure contains information to ensure the correct use of Xultophy to minimise the risk of medication errors. Main points include how to select the recommended starting dose, and how to perform dose adjustments.
https://www.medicines.org.uk/emc/product/3469/rmms

Xyzal (levocetirizine) tablets
Oculogyration has been added as a potential adverse effect of treatment (frequency unknown).
https://www.medicines.org.uk/emc/product/1537/smpc

Yentreve (duloxetine hydrochloride) hard gastro-resistant capsules (all strengths) and Cymbalta (duloxetine hydrochloride) hard gastro-resistant capsules (all strengths)
SPC revised to warn that duloxetine may cause symptoms of sexual dysfunction; stating there have been reports of long-lasting sexual dysfunction where the symptoms have continued despite discontinuation of treatment.
https://www.medicines.org.uk/emc/product/7441/smpc

Zimovane (zopiclone) 7.5mg film-coated tablets
Section 4.2 of the SPC now does not mention a specific duration for treatment and section 4.4 advises the cause of insomnia should be identified wherever possible and the underlying factors treated before a hypnotic is prescribed.
https://www.medicines.org.uk/emc/product/2855/smpc

Zinforo (ceftaroline) concentrate for solution for infusion
The SPC has been updated to reflect Ceftaroline is now licensed for use in children, including neonates. It is licensed for use in complicated skin and soft tissue infections, and community-acquired pneumonia, and the SPC has dosing information for paediatric use.
https://www.medicines.org.uk/emc/product/4297/smpc