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Medicines Safety Assurance Tool August 2017



MIDLANDS AND LANCASHIRE
COMMISSIONING SUPPORT UNIT

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Prescribing regular drugs to prevent febrile convulsions risks more harm than benefit

National Institute for Health Research | 01-August-2017

Expert commentary is provided for a systematic review which found that intermittent diazepam, but not other treatments, reduced the risk of recurrent febrile convulsions. Prophylactic treatment can have adverse effects, and although scary, recurrent febrile convulsions are benign.

<https://discover.dc.nihr.ac.uk/portal/article/4000735/prescribing-regular-drugs-to-prevent-febrile-convulsions-risks-more-harm-than-benefit>

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned** ▼

Date completed

Shortage of Adult Hepatitis B Vaccine

Central Alerting System | 07-August-2017

There is a global shortage of hepatitis B vaccine which is currently impacting severely on the UK supply. The situation is particularly critical during August but there is likely to still be some limitations on supply until early 2018. PHE have developed temporary recommendations to support clinicians undertaking an individual risk assessment to ensure that stock is available for those individuals at highest and most immediate risk of exposure to hepatitis B.

https://www.cas.dh.gov.uk/ViewAndAcknowledgment/viewAttachment.aspx?Attachment_id=102818

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned** ▼

Date completed

Adrenaline auto-injectors: updated advice after European review

Medicines and Healthcare products Regulatory Agency | 15-August 2017

It is recommended that 2 adrenaline auto-injectors are prescribed, which patients should carry at all times.

<https://www.gov.uk/drug-safety-update/adrenaline-auto-injectors-updated-advice-after-european-review>

Proposed action

- Newsletter
- Optimise Rx/ScriptSwitch
- Practice audit/search
- Other

Action taken

Status Unassigned ▼
Date completed

Corticosteroids: rare risk of central serous chorioretinopathy with local as well as systemic administration

Medicines and Healthcare products Regulatory Agency | 15-August 2017

Central serous chorioretinopathy is a retinal disorder that has been linked to the systemic use of corticosteroids. Recently, it has also been reported after local administration of corticosteroids via inhaled and intranasal, epidural, intra-articular, topical dermal, and periocular routes.

<https://www.gov.uk/drug-safety-update/corticosteroids-rare-risk-of-central-serous-chorioretinopathy-with-local-as-well-as-systemic-administration>

Proposed action

- Newsletter
- Optimise Rx/ScriptSwitch
- Practice audit/search
- Other

Action taken

Status Unassigned ▼
Date completed

Insulin pens: NovoPen Echo and NovoPen 5 (certain batches) - risk of hyperglycaemia due to cartridge holder weakening when exposed to certain household chemicals

Medicines and Healthcare products Regulatory Agency | 24-August 2017

Manufactured by Novo Nordisk - recall and replacement of specific batches of cartridge holder

<https://www.gov.uk/drug-device-alerts/insulin-pens-novopen-echo-and-novopen-5-certain-batches-risk-of-hyperglycaemia-due-to-cartridge-holder-weakening-when-exposed-to-certain-household-chemicals>

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned** ▼

Date completed

Differentiation of Mirena, Jaydess and Kyleena levonorgestrel intrauterine delivery systems

Bayer | 03-August-2017

Kyleena is a newly licensed levonorgestrel intrauterine delivery system (IUS), providing contraception for up to five years. This education pack highlights the differences between this and the other two Bayer IUS currently available in the UK (Jaydess and Mirena).

<http://www.medicines.org.uk/emc/RMM.1018.pdf>

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned** ▼

Date completed

Summary of Product Characteristics Update

electronic Medicines Compendium | August 2017

Aidulan (ethinylestradiol 20microg/ gestodene 75microg) film-coated tablets

SPC has been updated with contraindication for concomitant use with ombitasvir/paritaprevir/ritonavir and dasabuvir as ALT elevations higher than 5 times upper limit of normal have been reported in women using ethinylestradiol-containing medication with these drugs.

<http://www.medicines.org.uk/emc/medicine/31258>

Arava (leflunomide) 100mg Tablets

SPC now warns measurement of ionised calcium levels might show falsely decreased values with leflunomide and/or teriflunomide depending on type of ionised calcium analyser used. In case of doubtful measurements, total albumin adjusted serum calcium should be measured.

<http://www.medicines.org.uk/emc/medicine/26343>

Arava (leflunomide) tablets

Measurement of ionised calcium levels might show falsely decreased values in patients on leflunomide. In case of doubtful measurements, it is recommended to determine the total albumin adjusted serum calcium concentration.

<http://www.medicines.org.uk/emc/medicine/26344>

Calcichew Forte (calcium carbonate) Chewable Tablets

The tablets no longer contain aspartame (E951) or sorbitol (E420). The warning about the use of this product in patients with phenylketonuria has been removed.

<http://www.medicines.org.uk/emc/medicine/28503>

Cosopt Preservative-Free 20 mg/ml + 5 mg/ml, eye drops, solution in single-dose container

The shelf life has been increased to 30 months and the product should not be stored above 25°C.

<http://www.medicines.org.uk/emc/medicine/31335>

Cubicin (daptomycin) powder for concentrate for solution for injection or infusion

The SPC now notes that the adverse effect eosinophilic pneumonia occasionally presents as organising pneumonia [defined pathologically by the presence in the distal air spaces of buds of granulation tissue] (frequency unknown).

<http://www.medicines.org.uk/emc/medicine/17341>

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned** ▼
Date completed

Cuvitru (Human normal immunoglobulin) solution for subcutaneous injection

The manufacturers now highlight that that if the preparation remains in siliconized syringes for more than two hours, visible particles may form. It states that the infusion must be started immediately upon transfer into the syringe to prevent particulate formation.

<http://www.medicines.org.uk/emc/medicine/33220>

Daktarin (miconazole) Sugar Free 2% Oral Gel

The SPC now details the interaction with warfarin, and the product packaging has been updated to state that patients should not use if they are taking warfarin. Concomitant use can substantially increase INR, and fatal outcomes (due to bleeding) have been reported.

<http://www.medicines.org.uk/emc/medicine/22032>

Darzalex (daratumumab) 20 mg/mL concentrate for solution for infusion

Section 6.3 now advises that the unopened vials have a shelf life of 24 months (previously 18 months).

<http://www.medicines.org.uk/emc/medicine/32088>

Eumovate Ointment (0.05% w/w clobetasone butyrate)

Sections 4.4 and 4.8 have been updated to align to the PRAC recommendation with regard to blurred vision and central serous chorioretinopathy. Section 4.4 also now contains a statement relating to fire hazard in contact with dressings, clothing and bedding.

<http://www.medicines.org.uk/emc/medicine/2607>

Epanutin (phenytoin) Ready Mixed Parenteral

Sections 4.4 and 4.8 now include warnings about cardiovascular adverse effects, with asystole/cardiac arrest and bradycardia listed as possible adverse effects.

<http://www.medicines.org.uk/emc/medicine/14232>

Giotrif (afatinib) 20 mg/30 mg/40 mg/50 mg film-coated tablets

Nail disorder has been added to SPC as adverse effect of common frequency.

<http://www.medicines.org.uk/emc/medicine/28353>

Harvoni 90 mg/400 mg (ledipasvir and sofosbuvir) film-coated tablets

The indication has been extended to include treatment of chronic hepatitis C in adolescents aged 12 to < 18 years. Various other sections of the SPC have also been updated as a consequence.

<http://www.medicines.org.uk/emc/medicine/29471>

Januvia (sitagliptin) and Janumet (sitagliptin/metformin) tablets

SPC now highlights that there have been post-marketing reports of bullous pemphigoid in patients taking DPP-4 inhibitors including sitagliptin. If bullous pemphigoid is suspected, sitagliptin treatment should be discontinued.

<http://www.medicines.org.uk/emc/medicine/19609>

Keytruda (pembrolizumab) solution for infusion

Sections 4.2, 4.4 and 4.8 have been updated with information on immune-related skin adverse reactions including cases of Stevens-Johnson syndrome and toxic epidermal necrolysis, some with fatal outcome. Depending on severity, treatment should be withheld or discontinued.

<http://www.medicines.org.uk/emc/medicine/33162>

Loceryl Curanail (amorolfine) 5% w/v Medicated Nail Lacquer

Following post-marketing experience, systemic hypersensitivity has been added as a potential adverse effect of treatment (frequency unknown).

<http://www.medicines.org.uk/emc/medicine/17637>

Loceryl (amorolfine) Nail Lacquer 5%

SPC now highlights that after application, an interval of at least 10 min should be respected before application of any cosmetic nail lacquer. Before repeat application, the cosmetic nail lacquer should be removed carefully.

<http://www.medicines.org.uk/emc/medicine/6408>

Lynparza (olaparib) 50 mg hard capsules

Rash, hypersensitivity and dermatitis have been added to SPC as adverse events.

<http://www.medicines.org.uk/emc/medicine/30359>

Maxitrol (dexamethasone, polymyxin and neomycin) Ointment

SPC has been updated to warn that Cushing's syndrome and/or adrenal suppression linked to systemic absorption of ocular dexamethasone may occur after intensive or long-term continuous therapy. Also visual disturbance may be reported with systemic and topical corticosteroid use.

<http://www.medicines.org.uk/emc/medicine/70>

Moviprep, powder for oral solution

The details on the procedure for use is now separated into different sections for procedures under general anaesthesia and procedures without general anaesthesia.

<http://www.medicines.org.uk/emc/medicine/19285>

Munalea 150/30 (desogestrel/ethinylestradiol) micrograms Film-coated Tablets

Sections 4.3, 4.4 and 4.5 warns that Munalea should not be used by patients with hepatitis C taking ombitasvir/paritaprevir/ritonavir and dasabuvir. Concomitant use may increase the risk of ALT elevations; an alternative method of contraception must be considered.

<http://www.medicines.org.uk/emc/medicine/31009>

Olumiant (baricitinib) 2 mg and 4 mg Film-Coated Tablets

Section 4.4 now warns that events of DVT and PE have been reported in patients receiving baricitinib. It should be used with caution in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery and immobilisation

<http://www.medicines.org.uk/emc/medicine/32997>

ORENCIA (abatacept) 250 mg powder for concentrate for solution for infusion

Abatacept is now licensed, alone or with methotrexate (MTX), for the treatment of active psoriatic arthritis in adults when the response to previous DMARD, including MTX has been inadequate, and for whom additional systemic therapy for psoriatic skin lesions is not required.

<http://www.medicines.org.uk/emc/medicine/19714>

Oruvail (ketoprofen) 100mg capsules

Section 4.5 has been updated to include interactions with: heparin, vit K antagonists (e.g. warfarin), platelet aggregation inhibitors (e.g. ticlopidine, clopidogrel), thrombin inhibitors (e.g. dabigatran) and direct factor Xa inhibitors (e.g. apixaban, rivaroxaban, edoxaban).

<http://www.medicines.org.uk/emc/medicine/25505>

Otomize (neomycin/ dexamethasone)

SPC has been updated to warn visual disturbance may be reported with systemic/topical corticosteroid use. Patients with these ADRs should be considered for referral to ophthalmologist as causes may include cataract, glaucoma or rare diseases e.g. central serous chorioretinopathy.

<http://www.medicines.org.uk/emc/medicine/13699>

Perjeta (pertuzumab) 420 mg Concentrate for Solution for Infusion

Section 4.2 now advises that the infusion should be discontinued immediately and permanently if the patient experiences a NCI-CTCAE Grade 4 reaction (anaphylaxis), bronchospasm or acute respiratory distress syndrome.

<http://www.medicines.org.uk/emc/medicine/27473>

Praxbind (idarucizumab) 2.5 g/50 mL solution for injection/infusion

Sections 6.3 (Shelf life) and 6.4 (Special precautions for storage) of the SPC have been updated to reflect room temperature now defined as 30 degrees (previously 25 degrees).

<http://www.medicines.org.uk/emc/medicine/31243>

Qvar (beclomethasone) inhalers (all products)

SPCs revised to warn of possible systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat). Appropriate monitoring is advised with use of such agents, though beclomethasone is less dependent on CYP3A metabolism than other steroids

<http://www.medicines.org.uk/emc/medicine/23274>

Seebri (glycopyrronium) Breezhaler Inhalation Powder

Nausea, vomiting (both uncommon) and musculoskeletal pain (common) have been added as potential adverse reactions to treatment.

<http://www.medicines.org.uk/emc/medicine/27138>

Sirturo (bedaquiline fumarate) 100 mg tablets

Section 4.4 now advises that when bedaquiline is co administered with other medicinal products that prolong QTc interval (including delamanid and levofloxacin), an additive or synergistic effect on QT prolongation cannot be excluded. Caution is recommended.

<http://www.medicines.org.uk/emc/medicine/29644>

Soliris (eculizumab)

The indication has been updated to include treatment of adults with refractory generalized myasthenia gravis who are anti-acetylcholine receptor antibody-positive (information relating to this new indication has been added to various sections of the SPC).

<http://www.medicines.org.uk/emc/medicine/19966>

Temomedac (temozolomide) 140mg hard capsules

Following PRAC Recommendation, SPC has been updated with warning that post marketing cases of meningoencephalitis herpetic (including fatalities) has been observed in patients on temozolomide in combination with radiotherapy, including cases on concomitant steroids.

<http://www.medicines.org.uk/emc/medicine/23338>

Temomedac (temozolomide) 250mg hard capsules

Sections 4.4 and 4.8 note that post marketing cases of herpetic meningoencephalitis (including fatal cases) have been reported (frequency uncommon) in patients receiving temozolomide in combination with radiotherapy, including cases of concomitant steroid administration.

<http://www.medicines.org.uk/emc/medicine/23336>

TicoVac (tick-borne encephalitis vaccine) Junior 0.25 ml Suspension for injection in a pre-filled syringe

Guillain-Barré syndrome has been added to SPC as rare adverse effect.

<http://www.medicines.org.uk/emc/medicine/30334>

Toctino (alitretinoin) 10mg and 30mg soft capsules

Section 4.8 now lists photosensitivity reactions and nail disorders as new post marketing adverse reactions.

<http://www.medicines.org.uk/emc/medicine/21177>

Tyverb (lapatinib)

Stevens-Johnson syndrome and toxic epidermal necrolysis have been added to SPC as adverse effects of unknown frequency.

<http://www.medicines.org.uk/emc/medicine/20929>

Xalkori (crizotinib) 200mg and 250mg hard capsule

Section 4.1 now clarifies that crizotinib is to be used as monotherapy only, for anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer.

<http://www.medicines.org.uk/emc/medicine/27168>