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Medicines Safety Assurance Tool May 2017



MIDLANDS AND LANCASHIRE
COMMISSIONING SUPPORT UNIT

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

Educational Risk Minimisation Materials for Clexane (enoxaparin sodium)

NICE | 15-May-2017

‘Dear Healthcare Professional’ letter notes that enoxaparin is expressed both in international units (IU) of anti-Xa activity and in milligrams (mg); and that its use in severe renal impairment is not recommended. There is also further clarification on dose regimens for DVT/PE.

<http://www.medicines.org.uk/emc/RMM.825.pdf>

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned** ▼

Date completed

Educational Risk Minimisation Materials for Levetiracetam 100mg/ml oral solution

NICE | 12-May-2017

‘Dear Healthcare Professional’ letter covers overdose due to medication errors and how to reduce risk. Where cause of reported accidental overdosing was known, it was either due to use of inappropriate syringe or misunderstanding of caregiver about how to properly measure dose.

<http://www.medicines.org.uk/emc/RMM.823.pdf>

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned** ▼

Date completed

Risk management materials for Daxas (roflumilast) 500 micrograms film-coated tablets: Information for prescribers and patients

NICE | 09-May-2017

This document contains information for healthcare professionals describing key prescribing and monitoring information (especially monitoring weight) to consider when prescribing roflumilast.

<http://www.medicines.org.uk/emc/RMM.817.pdf>

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other



[Redacted area]

Action taken

[Redacted area]

Status **Unassigned** ▼

Date completed [Redacted area]

Finasteride: rare reports of depression and suicidal thoughts

NICE | 26-May-2017

We have received reports of depression and, in rare cases, suicidal thoughts in men taking finasteride 1 mg (Propecia) for male pattern hair loss. Be aware that depression is also associated with finasteride 5 mg (Proscar).

Advice for healthcare professionals:

- Since finasteride has been marketed there have been a number of spontaneous adverse drug reaction reports suggesting a possible link to depression, and in rare cases, suicidal thoughts
- Advise patients to stop finasteride 1 mg (Propecia) immediately if they develop depression and inform a healthcare professional
- Be aware that the product information for finasteride 5 mg (Proscar) already lists depression as a possible adverse reaction

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other



[Redacted area]

Action taken

[Redacted area]

Status **Unassigned** ▼

Date completed [Redacted area]

<https://www.gov.uk/drug-safety-update/finasteride-rare-reports-of-depression-and-suicidal-thoughts>

Accu-Chek® Insight insulin pumps - updated information for battery management

MHRA | 02-May-2017

Manufactured by Roche Diabetes Care – Replacement and update to MDA/2015/029 with new instructions to improve battery lifetime and prevent unexpected pump shut down or rapid battery depletion.

Action

- Identify all users of Accu-Chek Insight insulin pumps.
- Ensure that all patients and carers:
 - Receive the manufacturer’s Field Safety Notice (FSN)
 - Understand the instructions detailed in the FSN and follow the advice given by the manufacturer
 - Use Energizer® Ultimate lithium batteries (1.5V AAA / FR03) provided by the manufacturer and follow the steps described in the handling instructions in the FSN
- Contact Roche if you experience unexpected pump shut down or rapid battery depletion.
- Return the FSN acknowledgment form to Roche as currently the manufacturer hasn’t received enough responses.

https://www.cas.dh.gov.uk/ViewAndAcknowledgment/viewAttachment.aspx?Attachment_id=102722

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned** ▼

Date completed

Class 2 Medicines Recall: Sodium Cromoglicate 2% w/v 13.5 mL Eye Drops

CAS | 18-May-2017

FDC International Ltd is recalling the batches listed as a precautionary measure due to a precipitate observed in the bottles.

https://assets.publishing.service.gov.uk/media/591eb86be5274a5e5100005a/Sodium_Cromoglicate_13.5_mL_Eye_Drops.pdf

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned** ▼

Date completed

Medical Device Alert: All LIFEPAK 1000 automatic external defibrillators (AEDs) - risk of device shutting down unexpectedly during patient treatment and possible failure to deliver therapy

CAS | 18-May-2017

1. Identify all LIFEPAK 1000 defibrillators in your possession.
2. Ensure that all those responsible for the AED follow the instructions in the manufacturer's Field Safety Notice (FSN).
3. If you have already acted on this FSN, no further action is required.

[https://assets.publishing.service.gov.uk/media/591da3bd40f0b63e0b00005f/MDA - 2017-013_Final.pdf](https://assets.publishing.service.gov.uk/media/591da3bd40f0b63e0b00005f/MDA_-_2017-013_Final.pdf)

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned** ▼

Date completed

Public Health England: Management of infection guidance for primary care for consultation and local adaptation: Update

PHE | 10-May-2017

Following a review of new evidence detailing increased risk of spontaneous abortion with azithromycin, clarithromycin, metronidazole, tetracyclines, quinolones and sulphonamides PHE guidance has been updated on antibiotic use pregnancy.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/612743/Managing_common_infections.pdf

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned** ▼

Date completed

Trimethoprim and Methotrexate: never co-prescribe

CCG | 31-May-2017

The BNF states that there is an increased risk of haematological toxicity when methotrexate is given with trimethoprim (also with co-trimoxazole).

Several cases of severe bone marrow depression (some of which were fatal) have been reported in patients given low-dose methotrexate and trimethoprim or co-trimoxazole (sulfamethoxazole with trimethoprim).

This potentially fatal interaction can occur even with short courses or low doses of trimethoprim.

Pancytopenia has also been reported in a few patients given co-trimoxazole shortly after stopping methotrexate.

Bone marrow suppression can occur abruptly, leading to:

- Life threatening infections, as the body cannot produce leukocytes in response to invading bacteria and viruses.
- Anaemia due to a lack of red blood cells.
- Spontaneous severe bleeding due to a deficiency of platelets.

Prescribers should be aware that some information sources do not stress the importance of this interaction.

EMIS Web highlights this drug interaction with a high severity warning.

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status **Unassigned**

Date completed

SPC updates

NICE | 30-May-2017

Revised SPC: Anusol HC (bismuth, zinc oxide and hydrocortisone) preparations

SPC now highlights that visual disturbance has been reported with systemic and topical corticosteroid use.

Patients with such symptoms should be considered for ophthalmology referral.

<http://www.medicines.org.uk/emc/medicine/10493>

Revised SPC: Avelox (moxifloxacin) preparations

Sections 4.4 (special warnings and precautions) and 4.8 (undesirable effects) have been updated to include the adverse reaction vasculitis with a frequency very rare and to modify the warnings on hypersensitivity reactions and peripheral neuropathy.

<http://www.medicines.org.uk/emc/medicine/22827>

Proposed action

- Newsletter Optimise Rx/ScriptSwitch
 Practice audit/search Other

Action taken

Status Unassigned ▼

Date completed

Revised SPC: Briviact (brivaracetam) – all formulations

Section 4.8 warns reactions suggestive of immediate (Type I) hypersensitivity have been reported in a small number of brivaracetam patients during clinical development.

<https://www.medicines.org.uk/emc/medicine/31452>

Revised SPC: Budenofalk (budesonide) preparations

Various additions, including side-effects (blurred vision, aggression, psychomotor hyperactivity and anxiety). Interaction with CYP3A inhibitors (increased risk of systemic side-effects) and further detail in the pregnancy and breast-feeding sections.

<http://www.medicines.org.uk/emc/medicine/18725>

Revised SPC: Dalacin C (clindamycin) capsules

Dose modification is not necessary in renal or hepatic insufficiency (4.2). Amended warnings made on hypersensitivity and severe skin reactions (4.4). C. difficile colitis, anaphylactic shock, anaphylactic reaction, hypersensitivity and angioedema have been added as adverse events (4.8)

<http://www.medicines.org.uk/emc/medicine/12425>

Revised SPC: Diflucan (fluconazole) all formulations

Section 4.4 updated with information on QT prolongation, reported during post-marketing surveillance. Section 4.5 notes that administration of fluconazole with amiodarone may increase QT prolongation; caution therefore advised, notably with high dose fluconazole (800 mg).

<http://www.medicines.org.uk/emc/medicine/25675>

Revised SPC: Epanutin (phenytoin) – various presentations

Information regarding the potential need for dose modification in elderly patients, and dose modification and/or measurement of unbound phenytoin levels in patients with renal or hepatic diseases, hypoalbuminemia, and/or hyperbilirubinemia has been added.

<http://www.medicines.org.uk/emc/medicine/13289>

Revised SPC: Epanutin (phenytoin) Infatabs

Sections 4.2 and 4.4 now includes information regarding the potential need for dose modification and/or measurement of unbound phenytoin due to potential for elevated concentration of unbound phenytoin in patients with renal or hepatic diseases, and hypo/hyperalbuminaemia

<http://www.medicines.org.uk/emc/medicine/13303>

Revised SPC: Firmagon (degarelix) 120mg Injection

SPC updated to warn that serious injection site reactions were very rarely reported such as injection site infection, injection site abscess or injection site necrosis that could require surgical treatment/drainage.

<http://www.medicines.org.uk/emc/medicine/21701>

<http://www.medicines.org.uk/emc/medicine/21701>

Revised SPC: Forxiga (dapagliflozin propanediol monohydrate) 5 mg & 10 mg film coated tablets

Section 4.4 advises of an increase in cases of lower limb amputation (primarily of the toe) reported in ongoing long-term, clinical studies with another SGLT2 inhibitor, but it is unknown whether this constitutes a class effect. Counsel patients on routine preventative foot care.

<http://www.medicines.org.uk/emc/medicine/27188>

Revised SPC: Heminevrin (clomethiazole) 192 mg Capsules

Section 4.5 now warns of possible interactions with CYP2E1-substrates.

<http://www.medicines.org.uk/emc/medicine/33156>

Revised SPC: Invokana (canagliflozin) 100 mg and 300 mg film-coated tablets

Section 4.4 has been revised to include class labelling text on diabetic ketoacidosis - Rare cases of diabetic ketoacidosis, including life-threatening and fatal cases, have been reported in patients treated with SGLT2 inhibitors, including canagliflozin.

<http://www.medicines.org.uk/emc/medicine/28400>

Revised SPC: Jardiance (empagliflozin) 10 mg and 25 mg film-coated tablets

The SPC now notes (section 4.4) 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/28973>

Revised SPC: Nasonex (mometasone furoate monohydrate) 50 micrograms/actuation Nasal Spray, Suspension

Section 4.5 now includes information regarding the expected increased risk of systemic side effects after co-treatment with CYP3A inhibitors, including cobicistat-containing products. The combination should be avoided.

<http://www.medicines.org.uk/emc/medicine/9748>

Revised SPC: Nuvaring (etonogestrel and ethinylestradiol) vaginal delivery system

Sections 4.3, 4.4 and 4.5 contraindicate the co-administration of ombitasvir/paritaprevir/ritonavir and dasabuvir with ethinyloestradiol because of the increased risk of elevated ALT.

<http://www.medicines.org.uk/emc/medicine/21419>

Revised SPC: Octasa (mesalazine) 400mg MR Tablets

Pleurisy has been added as a potential adverse effect from treatment (frequency unknown).

<http://www.medicines.org.uk/emc/medicine/27094>

Revised SPC: Pradaxa (dabigatran etexilate) hard capsules – all strengths

The colour of Pradaxa caps have been changed according to dosage strength, as part of the worldwide harmonisation process. The 75mg cap is white, the 110mg cap is light blue and the 125mg cap is two-tone light blue/white. Sunset yellow colouring has been removed from the casing.

<http://www.medicines.org.uk/emc/medicine/20760>

Revised SPC: Soolantra (ivermectin) 10mg/g Cream

Contact dermatitis has been added as a potential adverse effect from treatment (frequency unknown).

<http://www.medicines.org.uk/emc/medicine/30353>

Revised SPC: Tresiba (insulin degludec) 100 units/mL, 200 units/mL Pre filled (FlexTouch), 100 units/mL Cartridge (Penfill)

Dosing information has been extensively revised: In patients with type 2 diabetes, dose reduction of 20% based on previous basal insulin dose followed by individual dosage adjustments should be considered when transferring from twice-daily basal insulin or from insulin glargine.

<http://www.medicines.org.uk/emc/medicine/27360>

Revised SPC: Vokanamet (canagliflozin with metformin) 50 mg/850 mg, 50 mg/1000 mg, 150 mg/850 mg and 150 mg/1000 mg film coated tablets

Section 4.4 has been revised to include class labelling text on diabetic ketoacidosis - Rare cases of diabetic ketoacidosis, including life-threatening and fatal cases, have been reported in patients treated with SGLT2 inhibitors, including canagliflozin.

<http://www.medicines.org.uk/emc/medicine/29368>

Revised SPC: Xigduo (dapagliflozin and metformin) film coated tablets

Section 4.4 contains new clinical information on risk of lower limb amputations; patients should be counselled on routine preventative foot care. Rash has been added as a common adverse event ($\geq 1/100$ to $< 1/10$).

<http://www.medicines.org.uk/emc/medicine/28667>

Revised SPC: Zyban (bupropion) 150 mg prolonged release tablets

Hyponatraemia has been added as an adverse event (frequency not known) to section 4.8.

<http://www.medicines.org.uk/emc/medicine/2948>