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Medicines Safety Assurance Tool April 2019

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Midlands and Lancashire
Commissioning Support Unit

Methotrexate: updated recommendations for conception and contraception

BNF eNewsletter | 01 Apr

Manufacturer advises effective contraception during and for at least 6 months after treatment in men and women.

https://www.medicinescomplete.com/#/content/bnf/_680195013#content%2Fbnf%2F_680195013%23pot-conceptionAndContraception

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

How to minimise the risks of medication errors with rivastigmine patches

Specialist Pharmacy Service | 01 Apr

This updated Q&A aims to raise awareness on the types of medication errors reported with rivastigmine patches, as well as highlighting strategies to improve medication safety on the prescribing and administration of these patches.

https://www.sps.nhs.uk/wp-content/uploads/2017/03/UKMI_QA_rivastigmine-patches_March19_Final.doc

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Pregabalin (Lyrica), gabapentin (Neurontin) and risk of abuse and dependence: new scheduling requirements from 1 April

Medicines and Healthcare Regulatory Agency | 17 Apr

Under the Misuse of Drugs Act 1971, pregabalin and gabapentin are classified as Schedule 3 drugs. Healthcare professionals are advised to evaluate patients for a history of drug abuse before prescribing and observe patients for development of signs of abuse and dependence.

<https://www.gov.uk/drug-safety-update/pregabalin-lyrica-gabapentin-neurontin-and-risk-of-abuse-and-dependence-new-scheduling-requirements-from-1-april>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Valproate medicines and serious harms in pregnancy: new Annual Risk Acknowledgement Form and clinical guidance from professional bodies to support compliance with the Pregnancy Prevention Programme

Medicines and Healthcare Regulatory Agency | 17 Apr

The Annual Risk Acknowledgement Form for the valproate Pregnancy Prevention Programme has been updated and should be used during annual specialist review of all women and girls of childbearing potential on valproate medicines.

<https://www.gov.uk/drug-safety-update/valproate-medicines-and-serious-harms-in-pregnancy-new-annual-risk-acknowledgement-form-and-clinical-guidance-from-professional-bodies-to-support-compliance-with-the-pregnancy-prevention-programme>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Yellow fever vaccine (Stamaril) and fatal adverse reactions: extreme caution needed in people who may be immunosuppressed and those 60 years and older

Medicines and Healthcare Regulatory Agency | 17 Apr

Following two fatal adverse reactions, yellow fever vaccine must not be given to anyone with a history of thymus dysfunction or who is immunosuppressed. Due to a substantially increased risk in people aged >60 years, a careful risk assessment should be conducted.

<https://www.gov.uk/drug-safety-update/yellow-fever-vaccine-stamaril-and-fatal-adverse-reactions-extreme-caution-needed-in-people-who-may-be-immunosuppressed-and-those-60-years-and-older>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Summary of Product Characteristics Update

Electronic Medicines Compendium | Apr 2019

Betmiga (mirabegron) prolonged-release tablets

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

<https://www.medicines.org.uk/emc/product/7540/smpc>

Bexsero Meningococcal Group B vaccine

SPC now details a licence extension for use of booster doses in individuals at continued risk of exposure to meningococcal disease.

<https://www.medicines.org.uk/emc/product/5168/smpc>

Cervarix (human papillomavirus vaccine) suspension for injection (all presentations)

SPCs now states that Cervarix may also be administered concomitantly with meningococcal serogroups A, C, W-135 and Y tetanus toxoid conjugate vaccine (MenACWY-TT).

<https://www.medicines.org.uk/emc/product/1177/smpc>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Epistatus 10 mg Oromucosal Solution

Carer instructions for administration updated to include considering instructions from prescriber or local guidelines in case of emergency medical assistance. Further information is provided on hepatic impairment and warning on risk from concomitant use of opioids now included.

<https://www.medicines.org.uk/emc/product/2679/smpc>

Forxiga (dapagliflozin) 5 mg film-coated tablets

Dapagliflozin 5mg is now licensed for use in type 1 diabetes mellitus as an adjunct to insulin in patients with BMI \geq 27 kg/m², when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy.

<https://www.medicines.org.uk/emc/product/2865/smpc>

Insuman (human insulin) – all products

The SPCs have been updated to delete reference to the re-usable insulin pen injector OptiPen used for the administration of Insuman 3 ml cartridges as it is no longer produced.

<https://www.medicines.org.uk/emc/product/4104/smpc>

Kepra (levetiracetam) film-coated tablets – all strengths

Section 4.2 of the SPC has been updated to provide clarification of dosing in renal impairment. Section 4.8 now categorises delirium and encephalopathy as rare adverse reactions to levetiracetam.

<https://www.medicines.org.uk/emc/product/2293/smpc>

Norimin (norethisterone, ethinylestradiol) tablets

In line with PRAC requirements, section 4.4 of the SPC advises that depressed mood/depression are known side effects of hormone contraceptive use, stating it can be serious and is a risk factor for suicidal behaviour/suicide. Women are advised to seek medical help in case of mood changes.

<https://www.medicines.org.uk/emc/product/1147/smpc>

Oxycodone products (OxyContin, OxyNorm, Longtec, Shortec)

SPCs updated to warn concomitant administration of oxycodone with serotonin agents, such as SSRIs or SNRIs, may cause serotonin toxicity (ST). Oxycodone should be used with caution and dose may need to be reduced in patients using these medications. Symptoms of ST are described.

<https://www.medicines.org.uk/emc/product/7679/smpc>

Steglatro (ertugliflozin L-pyroglyutamic acid) film-coated tablets (all strengths)

Section 4.4 of the SPC now provides further guidance on monitoring patients at higher risk of amputation events, counselling patients on the importance of preventative footcare and maintaining adequate hydration and when to consider withdrawing treatment.

<https://www.medicines.org.uk/emc/product/9803/smpc>

Suliqua (insulin glargine and lixisenatide) - HCP Guide - Important information on dosing

This dosing guide has been produced for this combination product has been produced by the manufacturers to reduce the risk of dosing errors. <https://www.medicines.org.uk/emc/rmm/1369/Document>

Synphase 500 microgram / 35 microgram tablets and 1 milligram / 35 microgram tablets (norethisterone and ethinylestradiol)

In line with PRAC requirements, section 4.4 advises that depressed mood/depression are known side effects of hormone contraceptive use, stating it can be serious and is a risk factor for suicidal behaviour/suicide. Women are advised to seek medical help in case of mood changes.

<https://www.medicines.org.uk/emc/product/1579/smpc>

Zirtek (cetirizine) Allergy 10 mg film-coated Tablets and 1mg/ml oral solution

SPCs revised to advise that prospectively collected data on pregnancy outcomes do not suggest potential for maternal or foetal/embryonic toxicity above background rates and that cetirizine passes into breast milk so a risk of side effects in breastfed infants cannot be excluded.

<https://www.medicines.org.uk/emc/product/6751/smpc>