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Medicines Safety Assurance Tool

Mar-19

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

NIHR Signal: Medication to reduce stomach acid may increase risk of hip fractures

National Institute for Health Research Signal | 06 Mar

Expert commentary is provided for a meta-analysis of 24 observational studies (total n=2,103,800) which found that PPIs increased the risk of hip fracture by 20%. The findings don't suggest stopping use of PPIs, but they should be used with caution, and no drug is totally safe. <https://discover.dc.nihr.ac.uk/content/signal-000743/medication-to-reduce-stomach-acid-may-increase-risk-of-hip-fractures>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

What is the sodium content of medicines?

Specialist Pharmacy Service | 06 Mar

This Q&A provides lists of preparations that could contain high levels of sodium, and so might be unsuitable for people with conditions associated with sodium retention (e.g hypertension, heart failure or renal impairment) or who are on a salt-restricted diet. <https://www.sps.nhs.uk/articles/what-is-the-sodium-content-of-medicines-2/>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Fluoroquinolone Antibiotics: New Restrictions and Precautions Due To Very Rare Reports Of Disabling And Potentially Long-Lasting Or Irreversible Side Effects

Central Alerting System | 21 Mar

See alert for new restrictions and precautions for fluoroquinolone antibiotics (ciprofloxacin, levofloxacin, moxifloxacin, ofloxacin) following a review of disabling, long-lasting or potentially irreversible adverse reactions affecting musculoskeletal (including tendonitis and tendon rupture) and nervous systems with fluoroquinolone antibiotics.

<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102852>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing needed?

Medicines and Healthcare products Regulatory Agency | 21 Mar

MHRA has issued new guidance on contraceptive methods and frequency of pregnancy testing to reduce inadvertent exposures during pregnancy in a woman taking a medicine of teratogenic potential.

<https://www.gov.uk/drug-safety-update/medicines-with-teratogenic-potential-what-is-effective-contraception-and-how-often-is-pregnancy-testing-needed>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Triptans and SSRI or SNRI antidepressants - is there an interaction?

Specialist Pharmacy Service | 27 Mar

This Q&A advises that using these antidepressants together may have additive effects on the serotonin system with potential for adverse effects. Clinical experience however indicates that combined use is normally uneventful and they can be co-prescribed if clinically required. <https://www.sps.nhs.uk/articles/triptans-and-ssri-or-snri-antidepressants-is-there-an-interaction/>

Proposed action

- Newsletter
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- Practice audit/search
- Other (please specify)



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Unassigned ▼

Action due date

Date completed

Direct Oral Anticoagulant (DOAC) Dosing in renal impairment

Drug and Therapeutics Bulletin | 28 Mar

In light of > 4,000 yellow card reports of DOAC-associated haemorrhagic events since their launch, the author of this editorial highlights the urgent need for national guidance to help clinicians prescribe DOACs safely, particularly for patients with declining renal function. <https://dtb.bmj.com/content/57/4/50>

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

Valproate and the Pregnancy Prevention Programme: exceptional circumstances

British Journal of General Practice | 29 Mar

This editorial argues that there are exceptional circumstances, and personal and practical implications, that have not been adequately considered in the MHRA's regulations on valproate prescribing. <https://bjgp.org/content/69/681/166>

Proposed action

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



Action taken

Status

Unassigned



Action due date

Date completed

NICE publishes a summary of its guidance and other safety advice on valproate

National Institute for Health and Care Excellence | 29 Mar

Summary sheet brings together existing information and advice on safe prescribing from other sources (e.g. MHRA safety alerts, BNF, SPCs and information from DVLA) with NICE's existing guideline recommendations, to produce easy to access, practical recommendations. <https://www.nice.org.uk/news/article/nice-publishes-a-summary-of-its-guidance-and-other-safety-advice-on-valproate>

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 | March 2019

Bexsero Meningococcal Group B vaccine for injection in pre-filled syringe

The SPC now states that Bexsero can be co-administered with meningococcal groups A, C, W, Y conjugate vaccine.

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

Carbimazole or thiamazole containing products, Educational Risk Minimisation Materials

This guide details risk of acute pancreatitis and need for immediate discontinuation, if this occurs. Materials also highlight strengthened evidence that these drugs are associated with an increased risk of congenital malformations, particularly if given in the first trimester. <https://www.medicines.org.uk/emc/product/4266/rmms>

Clenil Modulite (beclometasone dipropionate) – all strengths

Section 4.2 of the SPC now advises there is now a dose indicator on the back of the inhaler which shows how many puffs are left. The number of puffs remaining is displayed in intervals of 20. A replacement inhaler should be ordered when indicator shows 20.

<https://www.medicines.org.uk/emc/product/6974/smpc>

Coracten XL 30mg and Coracten SR 10mg (nifedipine) capsules

SPC updated to include reports of pulmonary oedema (frequency not known) when used as tocolytic during pregnancy.

<https://www.medicines.org.uk/emc/product/5573/smpc>

Glycopyrronium Bromide 1 mg/5 ml Oral Solution

The SPC has been updated with new indication of symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.

<https://www.medicines.org.uk/emc/product/7344/smpc>

Invokana (canagliflozon) tablets

Necrotising fasciitis of the perineum has been added as a potential adverse effect of treatment (frequency unknown). Patients should seek medical attention if they experience a combination of pain, tenderness, erythema, or swelling in the genital area, with fever or malaise.

<https://www.medicines.org.uk/emc/product/8855/smpc>

Proposed action

Newsletter

Optimise Rx/ScriptSwitch

Practice audit/search

Other (please specify)

Action taken

Status

Unassigned

Action due date

Date completed



Keppra (levetiracetam) products

The SPC has been revised to advise that levetiracetam can be used during pregnancy, if after careful assessment it is considered clinically needed; in such case, lowest effective dose is recommended. It also now warns that after oral administration a bitter taste may be experienced.

<https://www.medicines.org.uk/emc/product/2295/smpc>

Levosert (levonorgestrel) 20 micrograms/24 hours Intrauterine Delivery System

The SPC updated to advise depression can be a serious undesirable effect of treatment and is a well-known risk factor for suicidal behaviour and suicide. Women should be advised to contact their physician in case of any mood changes and/or depressive symptoms.

<https://www.medicines.org.uk/emc/product/1789/smpc>

Mizollen (mizolastine) 10 mg modified-release tablets

Vomiting has been added as an adverse effect (unknown frequency) to the SPC.

<https://www.medicines.org.uk/emc/product/363/smpc>

Nuvaring (etonogestrel and ethinylestradiol) vaginal delivery system

The SPC now details that there have been reports of ring breakage during concomitant use of intravaginal preparations, including antimycotic, antibiotic and lubricant products.

<https://www.medicines.org.uk/emc/product/6449/smpc>

Priligy (dapoxetine) 30 and 60 mg film-coated tablets

The SPC has been updated to warn that as grapefruit juice is also a potent CYP3A4 inhibitor, it should be avoided within 24 hours prior to taking dapoxetine.

<https://www.medicines.org.uk/emc/product/7420/smpc>

Resolor (prucalopride) 1mg film-coated tablets

Migraine and vertigo have been added to SPC as uncommon adverse events

<https://www.medicines.org.uk/emc/product/584/smpc>

Restandol Testocaps (testosterone) caps

Section 4.4 of the SPC has been updated to highlight warnings relating to drug abuse and dependence. Abuse can lead to serious adverse effects including cardiovascular (with fatal outcomes in some cases), hepatic and or psychiatric events.

<https://www.medicines.org.uk/emc/product/1603/smpc>

Scheriproct Ointment (cinchocaine with prednisolone)

The SPC has been updated to provide information on changes to the intended use of the rectal applicator from single-use to multi-use and to recommend a validated cleaning procedure for the applicator which is prerequisite for multiple use.

<https://www.medicines.org.uk/emc/product/283/smpc>

Tarivid (ofloxacin) 400mg film-coated tablets

The SPC advises that an increased risk of aortic aneurysm and dissection after intake of fluoroquinolones, particularly in the older population has been reported. Therefore, fluoroquinolones should only be used after careful risk- assessment.

<https://www.medicines.org.uk/emc/product/8687/smpc>

Xyzal (levocetirizine) 5mg Tablets

Nightmare has been added to SPC as an adverse effect of unknown frequency.

<https://www.medicines.org.uk/emc/product/1537/smpc>

Zantac (ranitidine) Tablets 300mg

The SPC has been updated to include dosing information for use in oesophageal reflux disease

<https://www.medicines.org.uk/emc/product/220/smpc>

Zyloric (allopurinol) tablets – all strengths

Anaphylactic reaction has been added to the SPC as a very rare adverse drug reaction.

<https://www.medicines.org.uk/emc/product/1312/smpc>